

EPA Registration File No. 59106-8

Material Sent for Data Extraction

Reg # 59106-8

Description: New Product

☒ Material(s) Sent to Data Extraction Contractors:

☒ New Stamped Label Dated 7/24/14

☐ Notification Dated _____

☒ New CSF(s) Dated 7/14/2014

☐ Other: _____

☒ Decision #: 487386

☐ Other Action/Comments: _____

Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer: Tracy Lantz

Phone: 703 308 6415 Division: AD

Date: 8/25/14

Created February 3, 2011



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

EPA Reg. Number:

59106-8

Date of Issuance:

JUL 24 2014

Term of Issuance:

Unconditional

Name of Pesticide Product:

BioClear G50 Antimicrobial

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Clearwater International, LLC
D/B/A Weatherford Engineered Company
2000 St. James Place, 7th Floor
Houston, TX 770956

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

The application referred to above, submitted under the Federal Insecticide, Fungicide and Rodenticide Act, as amended is acceptable under FIFRA sec. 3(c)(5). Please note, you are required to submit and/or cite all data required for registration/reregistration/registration review of your product when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Eric Miederhoff
Acting Product Manager (33)
Regulatory Management Branch 1
Antimicrobials Division (7510P)

Date:

JUL 24 2014



BioClear G50 Antimicrobial

FOR MANUFACTURING USE ONLY

Active ingredient

Glutaraldehyde.....51.1%

Inert ingredients.....48.9%

Total.....100%

PRECAUTIONARY STATEMENTS HAZARD TO HUMANS AND DOMESTIC ANIMALS

DANGER

Keep Out of Reach of Children

DANGER! Corrosive. Causes irreversible eye damage. Causes skin burns. Harmful if inhaled. May be fatal if swallowed. Harmful if absorbed through skin. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Causes asthmatic symptom in hyper-sensitive individuals.

Do not get in eyes, on skin or on clothing. Do not swallow. Avoid breathing vapor. Wear goggles or face shield and protective clothing and glove made of butyl or nitrile rubber. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

Handle in a well-ventilated area. If vapors are irritating to the nose or eyes, special ventilation or respiratory protection (MSHA/NIOSH approved air purifying respirator equipped with an organic vapor cartridge) may be required.

ENVIRONMENTAL HAZARDS

This product is toxic to fish, aquatic invertebrates, oysters and shrimp. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

Manufactured for:
CLEARWATER INTERNATIONAL, LLC
D/B/A WEATHERFORD ENGINEERED
CHEMISTRY
2000 St. James Place
Houston, TX 77056
713-836-4000

STORAGE AND HANDLING

BIOCLEAR G50 Antimicrobial is incompatible with many commonly used materials of construction such as steel, galvanized iron, aluminum, tin, and zinc. BIOCLEAR G50 Antimicrobial can be stored and handled in baked phenolic-lined steel, polyethylene, stainless steel, or reinforced epoxy-plastic equipment. This product freezes at about 27 °F (-3 °C). Therefore, unless the storage tank is inside or underground, heating and insulation may be required. If heating is needed, exposure to high temperatures should be avoided. For short storage times (up to about 1 month), temperatures of up to 100 °F (37.8 °C) can be tolerated but the preferred maximum storage temperature is about 80 °F (26.7 °C). A stainless steel centrifugal pump is suggested for transfer service. Spiral-wound stainless steel with TEFLON[®] Polymer is suitable for gaskets and packing.

STORAGE AND DISPOSAL

PESTICIDE DISPOSAL: Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL

Non-refillable container: Do not reuse or refill this container. Triple rinse or pressure rinse container (or equivalent) promptly after emptying. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

Refillable Container: Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning of the container is the responsibility of the person disposing of the container. Cleaning the container before refilling is the responsibility of the person refilling the container. To clean the container before final disposal, empty contents into application equipment and triple rinse. Pour or pump rinsate into application equipment or rinsate collection system. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

EPA registration # 59106-8

EPA establishment #: _____

Net contents: _____ LBS. _____ KG.

First Aid

If swallowed:	• Call a poison control center or doctor immediately for treatment advice. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything to drink.
If in eyes:	• Hold eye open and rinse immediately and completely with water for at least 30 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Obtain prompt medical consultation. • Call a poison control center or doctor for treatment advice.
If on skin or clothing	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
If inhaled	• Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For emergency information call the National Pesticides Information Center at 1-900-858-7378, 8:30 AM to 4:30 PM Pacific Time (PT), seven days a week. During other times, call the poison control center at 1-800-222-1222.

DIRECTIONS FOR USE

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For use in the formulation of antimicrobial Products in the following applications:

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- Drilling, completion and workover fluids
- Packer fluids
- Gas storage
- Hydrotesting
- Pipeline
- Frac fluids
- Water floods

Industrial Processes and Water Systems

- Air washers
- Service water and ancillary non-potable systems
- Heat transfer systems
- Industrial wastewater systems including those with reverse osmosis membranes
- Aqueous metal working systems

ACCEPTED

07/24/2014

Under the Federal Insecticide, Fungicide,
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 59106-8

Lantz, Tracy

From: Oslosky, Stanley <Stanley.Oslosky@Weatherford.com>
Sent: Wednesday, July 30, 2014 3:05 PM
To: Miederhoff, Eric
Cc: Lantz, Tracy
Subject: RE: 59106-8 & 9

Thanks Eric and Tracy,

Stan

From: Miederhoff, Eric [mailto:Miederhoff.Eric@epa.gov]
Sent: Friday, July 25, 2014 3:13 PM
To: Oslosky, Stanley
Cc: Lantz, Tracy
Subject: RE: 59106-8 & 9

Stan,

Attached find the stamped labels and Reg. notices.

Regards,

Eric Miederhoff
Acting Product Manager, Team 33
Regulatory Management Branch I
Antimicrobials Division
Office of Pesticide Programs
Environmental Protection Agency
703-347-8028

From: Oslosky, Stanley [mailto:Stanley.Oslosky@Weatherford.com]
Sent: Thursday, July 24, 2014 5:25 PM
To: Miederhoff, Eric
Subject: RE: 59106-O

Eric,

Thank you for your patience.

Regards,

Stan

From: Miederhoff, Eric [mailto:Miederhoff.Eric@epa.gov]
Sent: Thursday, July 24, 2014 5:13 PM

To: Oslosky, Stanley
Subject: RE: 59106-O

Stan,

Thank you for these last few adjustments, the ppm ranges look fine now. I'm signing the registration notices for these today, I'll email them and the stamped labels to you tomorrow.

Eric Miederhoff
Acting Product Manager, Team 33
Regulatory Management Branch I
Antimicrobials Division
Office of Pesticide Programs
Environmental Protection Agency
703-347-8028

From: Oslosky, Stanley [<mailto:Stanley.Oslosky@Weatherford.com>]
Sent: Thursday, July 24, 2014 5:01 PM
To: Miederhoff, Eric
Subject: 59106-O

Eric,

This should get it. Let me know.

Stan
724-316-0689

This message may contain confidential and privileged information. If it has been sent to you in error, please reply to advise the sender of the error and then immediately delete it. If you are not the intended recipient, do not read, copy, disclose or otherwise use this message. The sender disclaims any liability for such unauthorized use. PLEASE NOTE that all incoming e-mails sent to Weatherford e-mail accounts will be archived and may be scanned by us and/or by external service providers to detect and prevent threats to our systems, investigate illegal or inappropriate behavior, and/or eliminate unsolicited promotional e-mails (spam). This process could result in deletion of a legitimate e-mail before it is read by its intended recipient at our organization. Moreover, based on the scanning results, the full text of e-mails and attachments may be made available to Weatherford security and other personnel for review and appropriate action. If you have any concerns about this process, please contact us at dataprivacy@weatherford.com.

Lantz, Tracy

From: Miederhoff, Eric
Sent: Friday, July 25, 2014 8:32 AM
To: Lantz, Tracy
Subject: RE: URGENT FW: 59106-I and 59106-O Label corrections

Categories: Red Category, PRINT THIS

Hi Tracy,

Thanks for the note, I had some last minute issues to work out with Stan, but we got these guys signed yesterday.

Thanks for your good work on these, enjoy your vacation!

Eric

From: Lantz, Tracy
Sent: Thursday, July 24, 2014 8:11 AM
To: Miederhoff, Eric
Subject: URGENT FW: 59106-I and 59106-O Label corrections

Hi Eric,

I am enjoying my vacation and hope all is well at the office.
Were you able to get these two products registered? I believe they are due out today.
They should be longer out of OPPIN by today as completed.

Thanks,

Tracy Lantz
Antimicrobials Division
Office of Pesticide Programs
Environmental Protection Agency
(703) 308-6415
Lantz.tracy@epa.gov

From: Oslosky, Stanley [<mailto:Stanley.Oslosky@Weatherford.com>]
Sent: Friday, July 11, 2014 4:30 PM
To: Miederhoff, Eric; Lantz, Tracy
Subject: RE: 59106-I and 59106-O Label corrections

Eric,

I received a response from the QC manager regarding the range of effectiveness of the enforcement analytical method for the above referenced products. I have attached it and have appended it to the method itself and revised the confidential chemistry volume and have also attached that.
Let me know if you need anything else.

Regards,

Stan
724-316-0689

From: Miederhoff, Eric [<mailto:Miederhoff.Eric@epa.gov>]
Sent: Friday, July 11, 2014 12:50 PM
To: Oslosky, Stanley; Lantz, Tracy
Subject: RE: 59106-I and 59106-O Label corrections

Stan,

Thanks for letting me know. Monday should be fine.

Enjoy the weekend,

Eric Miederhoff
Acting Product Manager, Team 33
Regulatory Management Branch I
Antimicrobials Division
Office of Pesticide Programs
Environmental Protection Agency
703-347-8028

From: Oslosky, Stanley [<mailto:Stanley.Oslosky@Weatherford.com>]
Sent: Friday, July 11, 2014 12:45 PM
To: Lantz, Tracy; Miederhoff, Eric
Subject: RE: 59106-I and 59106-O Label corrections

Eric,

I running into vacations at the analytical lab. May be until Monday. I sure that the method works at the 50% level, but need to get an analytical person to write up an addendum to the study.

Regards,

Stan
724-316-0689

This message may contain confidential and privileged information. If it has been sent to you in error, please reply to advise the sender of the error and then immediately delete it. If you are not the intended recipient, do not read, copy, disclose or otherwise use this message. The sender disclaims any liability for such unauthorized use. PLEASE NOTE that all incoming e-mails sent to Weatherford e-mail accounts will be archived and may be scanned by us and/or by external service providers to detect and prevent threats to our systems, investigate illegal or inappropriate behavior, and/or eliminate unsolicited promotional e-mails (spam). This process could result in deletion of a legitimate e-mail before it is read by its intended recipient at our organization. Moreover, based on the scanning results, the full text of e-mails and attachments may be made available to Weatherford security and other personnel for review and appropriate action. If you have any concerns about this process, please contact us at dataprivacy@weatherford.com.

Lantz, Tracy

From: Oslosky, Stanley <Stanley.Oslosky@Weatherford.com>
Sent: Thursday, July 10, 2014 6:09 PM
To: Lantz, Tracy
Cc: Miederhoff, Eric
Subject: RE: 59106-I and 59106-O Label corrections
Attachments: 059106-00008.20140710.BioClear G50 Antimicrobial.pdf;
059106-00009.20140710.BioClear 2500 Antimicrobial.pdf; MRID clarification.pdf

Categories: PRINT THIS

Tracy/Eric,

Enclosed are the renamed labels with the registration number corrected and a letter explaining my intent to cover only one source with the "preliminary analysis.

Thanks and regards,

Stan
724-316-0689

This message may contain confidential and privileged information. If it has been sent to you in error, please reply to advise the sender of the error and then immediately delete it. If you are not the intended recipient, do not read, copy, disclose or otherwise use this message. The sender disclaims any liability for such unauthorized use. PLEASE NOTE that all incoming e-mails sent to Weatherford e-mail accounts will be archived and may be scanned by us and/or by external service providers to detect and prevent threats to our systems, investigate illegal or inappropriate behavior, and/or eliminate unsolicited promotional e-mails (spam). This process could result in deletion of a legitimate e-mail before it is read by its intended recipient at our organization. Moreover, based on the scanning results, the full text of e-mails and attachments may be made available to Weatherford security and other personnel for review and appropriate action. If you have any concerns about this process, please contact us at dataprivacy@weatherford.com.



Weatherford*

BioClear G50 Antimicrobial

FOR MANUFACTURING USE ONLY

Active ingredient

Glutaraldehyde.....51.1%
Inert ingredients.....48.9%
Total..... 100%

PRECAUTIONARY STATEMENTS HAZARD TO HUMANS AND DOMESTIC ANIMALS

DANGER

Keep Out of Reach of Children

DANGER! Corrosive. Causes irreversible eye damage. Causes skin burns. Harmful if inhaled. May be fatal if swallowed. Harmful if absorbed through skin. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Causes asthmatic symptom in hyper-sensitive individuals.

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Handle in a well-ventilated area. If vapors are irritating to the nose or eyes, special ventilation or respiratory protection (MSHA/NIOSH approved air purifying respirator equipped with an organic vapor cartridge) may be required.

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Manufactured for:

CLEARWATER INTERNATIONAL, LLC
D/B/A WEATHERFORD ENGINEERED
CHEMISTRY
2000 St. James Place
Houston, TX 77056
713-836-4000

STORAGE AND HANDLING

BIOCLEAR G50 Antimicrobial is incompatible with many commonly used materials of construction such as steel, galvanized iron, aluminum, tin, and zinc. BIOCLEAR G50 Antimicrobial can be stored and handled in baked phenolic-lined steel, polyethylene, stainless steel, or reinforced epoxy-plastic equipment. This product freezes at about 27 °F (-3 °C). Therefore, unless the storage tank is inside or underground, heating and insulation may be required. If heating is needed, exposure to high temperatures should be avoided. For short storage times (up to about 1 month), temperatures of up to 100 °F (37.8 °C) can be tolerated but the preferred maximum storage temperature is about 80 °F (26.7 °C). A stainless steel centrifugal pump is suggested for transfer service. Spiral-wound stainless steel with TEFLON® Polymer is suitable for gaskets and packing.

STORAGE AND DISPOSAL

PESTICIDE DISPOSAL: Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL

Non-refillable container: Do not reuse or refill this container. Triple rinse or pressure rinse container (or equivalent) promptly after emptying. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

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EPA registration # 59106-8

EPA establishment #: _____

Net contents: ____ LBS. ____ KG.

First Aid

If swallowed:	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything to drink.
If in eyes:	<ul style="list-style-type: none"> • Hold eye open and rinse immediately and completely with water for at least 30 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Obtain prompt medical consultation. • Call a poison control center or doctor for treatment advice.
If on skin or clothing	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
If Inhaled	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For emergency information call the National Pesticides Information Center at 1-800-858-7378, 6:30 AM to 4:30 PM Pacific Time (PT), seven days a week. During other times, call the poison control center at 1-800-222-1222.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

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For use in the formulation of antimicrobial Products in the following applications:

Oil Field Preservatives

- Oil and gas production
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- Packer fluids
- Gas storage
- Hydrotesting
- Pipeline
- Frac fluids
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Industrial Processes and Water Systems

- Air washers
- Service water and ancillary non-potable systems
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- Industrial wastewater systems including those with reverse osmosis membranes
- Aqueous metal working systems



Office of Pesticide Programs (7504P)
U. S. Environmental Protection Agency
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

July 10, 2014

ATTENTION: Tracy Lantz
Product, Team 33

SUBJECT: MRID# 49310102
Clearwater International, LLC d/b/a Weatherford Engineered Chemistry (59106)
BioClear G50 Antimicrobial and BioClear 2500 Antimicrobial

Dear Tracy;

This correspondence is to certify that the above reference MRID# is intended to apply only to one source, the following [REDACTED] source:

[REDACTED]

In my discussions with Eric, apparently my filing of an alternate formula with the intent that I could also use my registration 59106-I to produce 59106-O caused some confusion in to what the preliminary analysis was to apply. Be assured that we are currently registering only the one [REDACTED] source.

Thank you for your assistance with this application and if you or your staff have any other questions, please call me at 724-316-0689 or e-mail me at Stanley.oslosky@weatherford.com.

Sincerely,

Stan Oslosky
Consultant to Weatherford
Stanley.Oslosky@weatherford.com

CC: Eric Meiderhoff

Engineered Chemistry

Weatherford
2000 St. James Place
Houston, Texas 77056
USA

+1.713.968.4000
+1.713.969.2401 Fax

www.weatherford.com



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revised 7/8/14

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If inhaled	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.

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Handle in a well-ventilated area. If vapors are irritating to the nose or eyes, special ventilation or respiratory protection (MSHA/NIOSH approved air purifying respirator equipped with an organic vapor cartridge) may be required.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewer treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

Manufactured for:
CLEARWATER INTERNATIONAL, LLC
D/B/A WEATHERFORD ENGINEERED
CHEMISTRY

2000 St. James Place
Houston, TX 77056
713-836-4000

STORAGE AND HANDLING

BIOCLEAR G50 Antimicrobial is incompatible with many commonly used materials of construction such as steel, galvanized iron, aluminum, tin, and zinc. **BIOCLEAR G50** Antimicrobial can be stored and handled in baked phenolic-lined steel, polyethylene, stainless steel, or reinforced epoxy-plastic equipment. This product freezes at about 27 °F (-3 °C). Therefore, unless the storage tank is inside or underground, heating and insulation may be required. If heating is needed, exposure to high temperatures should be avoided. For short storage times (up to about 1 month), temperatures of up to 100 °F (37.8 °C) can be tolerated but the preferred maximum storage temperature is about 80 °F (26.7 °C). A stainless steel centrifugal pump is suggested for transfer service. Spiral-wound stainless steel with **TEFLON**® Polymer is suitable for gaskets and packing.

STORAGE AND DISPOSAL

PESTICIDE DISPOSAL: Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL

Non-refillable container: Do not reuse or refill this container. Triple rinse or pressure rinse container (or equivalent) promptly after emptying. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

Refillable Container: Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning of the container is the responsibility of the person disposing of the container. Cleaning the container before refilling is the responsibility of the person refilling the container. To clean the container before final disposal, empty contents into application equipment and triple rinse. Pour or pump rinseate into application equipment or rinseate collection system. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

First Aid

If swallowed:	<ul style="list-style-type: none"> ● Call a poison control center or doctor immediately for treatment advice. ● Do not induce vomiting unless told to do so by the poison control center or doctor. ● Do not give anything to drink.
If in eyes:	<ul style="list-style-type: none"> ● Hold eyes open and rinse immediately and completely with water for at least 30 minutes. ● Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Obtain prompt medical consultation. ● Call a poison control center or doctor for treatment advice
If on skin or clothing	<ul style="list-style-type: none"> ● Take off contaminated clothing. ● Rinse skin immediately with plenty of water for 15-20 minutes. ● Call a poison control center or doctor for treatment advice
If inhaled	<ul style="list-style-type: none"> ● Move person to fresh air. ● If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. ● Call a poison control center or doctor for further treatment advice.

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For emergency information call the National Pesticides Information Center at 1-900-858-7378, 6:30 AM to 4:30 PM Pacific Time (PT), seven days a week. During other times, call the poison control center at 1-800-222-1222.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This product may be used for the formulation of pesticide products. Formulators using this product are responsible for obtaining EPA registrations for their formulated products.

For use in the formulation of antimicrobial Products in the following applications:

Oil Field Preservatives

- Oil and gas production
- Drilling, completion and workover fluids
- Packer fluids
- Gas storage
- Hydrotesting
- Pipeline
- Frac fluids
- Water floods

Industrial Processes and Water Systems

- Air washers
- Service water and ancillary non-potable systems
- Heat transfer systems
- Industrial wastewater systems including those with reverse osmosis membranes
- Aqueous metal working systems

EPA registration # 59106-XX
EPA establishment #:

Net contents: LBS. KG.

revise
per RED p. 67

Correct

MUF

rec'd extension
7/2/14

↓
will need revised
version of
reg # before
registration

me-too is
464-6911

may rely on box
data of 464-691

include
me too is:
464-694

Supported for AI? Directions on EOP?

REGULATION
1 2 3 4 5 6 7 8 9 0



Office of Pesticide Programs (7504P)
U. S. Environmental Protection Agency
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

July 10, 2014

ATTENTION: Tracy Lantz
Product, Team 33

SUBJECT: MRID# 49310102
Clearwater International, LLC d/b/a Weatherford Engineered Chemistry (59106)
BioClear G50 Antimicrobial and BioClear 2500 Antimicrobial

Dear Tracy;

This correspondence is to certify that the above reference MRID# is intended to apply only to one source, the following [REDACTED] source:

[REDACTED]

In my discussions with Eric, apparently my filing of an alternate formula with the intent that I could also use my registration 59106-I to produce 59106-O caused some confusion in to what the preliminary analysis was to apply. Be assured that we are currently registering only the one [REDACTED] source.

Thank you for your assistance with this application and if you or your staff have any other questions, please call me at 724-316-0689 or e-mail me at Stanley.oslosky@weatherford.com.

Sincerely,

Stan Oslosky
Consultant to Weatherford
Stanley.Oslosky@weatherford.com

CC: Eric Meiderhoff

Engineered Chemistry

Weatherford
2000 St. James Place
Houston, Texas 77056
USA

+1.713.968.4000
+1.713.969.2401 Fax

www.weatherford.com

Lantz, Tracy

59106-I

From: Oslosky, Stanley <Stanley.Oslosky@Weatherford.com>
Sent: Monday, April 21, 2014 4:58 PM
To: Lantz, Tracy
Subject: RE: 59106-I 10 day letter
Attachments: BC G50 Deficiency response compiled docx..pdf; CoverLetter_BC G50.pdf; Detailed Chemistry_BC G50.pdf; Transmittal Document BC G50.pdf; Waiver Request Chemistry_Vol 2_BC G50.pdf

Categories: Red Category

Tracy,

This is an e-mail copy of the documents in response to the e-mail below. I have included, for convenience a compiled copy of the total submission as one document as well as each document individually as a separate pdf. As stated in the cover letter a copy of the viscosity study is expected by the end of the week and to you by the 28th.

Call me with any concerns

Stan Oslosky
Consultant to Weatherford
724-316-0689

-----Original Message-----

From: Lantz, Tracy [mailto:Lantz.Tracy@epa.gov]
Sent: Thursday, April 10, 2014 6:30 PM
To: Oslosky, Stanley
Cc: Swindell, Marshall
Subject: FW: 59106-I 10 day letter

Please confirm that you have received this correspondence.

Please see the attached letter signed by Marshall Swindell.
The text of this letter is repeated below.

OPP Decision Number: 487386
EPA Reg. Number: 59106-I
Product Name: BioClear G50
EPA Receipt Date: February 3, 2014
EPA Company Number: 59106
Company Name: Clearwater International LLC d/b/a Weatherford Engineered Chemistry

Stan Oslosky
Consultant to Weatherford
2000 St. James Place, 7th Floor
Houston, TX 77056

Dear Mr. Oslosky:

The Agency has completed its preliminary technical screening of your application pursuant to Section 33(f)(4)(B)(i)(II) of the Federal Insecticide, Fungicide, and Rodenticide (FIFRA) Act, as amended by the Pesticide Registration Improvement

Tracy's copies



gave copies to

Chris V.

on 5/7/14

Extension Act. The Agency has determined that your application has not passed the preliminary technical screen and therefore is subject to rejection if the application is not corrected.

The submission has failed the Technical Screen for the following reasons:

You have indicated that this product is a me-too of 464-691. Based on the formulation submitted for this product, BioClear G50 is NOT a me-too of 464-691.

The following chemistry guidelines have not been addressed. These guideline must be addressed in order for EPA to continue the review of this application: 830.1900, 830.6314, 830.6315, 830.6316, 830.6317, 830.6319, 830.6320, and 830.7100. You may indicate that the data associated with 830.6317 and 830.6320 will be submitted for review at a later date.

In order for the review of your product to continue, you will need to correct your application by addressing the item(s) listed above within 10 business days of the date you received this letter. Corrections must be received by EPA by the 10th business day. EPA recommends sending your complete set of corrections by email to the contact listed below to ensure they are timely received. If studies or confidential information are being submitted by mail, a complete courtesy copy received by email by the deadline will be considered timely. If you cannot correct the application [or do not respond] within 10 business days, your application will be rejected.

At this time you could also choose to withdraw your application. If you have questions, please contact Marshall Swindell at Swindell.marshall@epa.gov or (703) 308-6341 or Tracy Lantz at Lantz.tracy@epa.gov or (703) 308-6415.

Tracy Lantz
Antimicrobials Division
Office of Pesticide Programs
Environmental Protection Agency
(703) 308-6415
Lantz.tracy@epa.gov

-----Original Message-----

From: EZTech_Printer [<mailto:EZTek@epa.gov>]
Sent: Thursday, April 10, 2014 6:22 PM
To: Lantz, Tracy
Subject: 59106-I 10 day letter

Please open the attached document. This document was digitally sent to you using an HP Digital Sending device. This message may contain confidential and privileged information. If it has been sent to you in error, please reply to advise the sender of the error and then immediately delete it. If you are not the intended recipient, do not read, copy, disclose or otherwise use this message. The sender disclaims any liability for such unauthorized use. PLEASE NOTE that all incoming e-mails sent to Weatherford e-mail accounts will be archived and may be scanned by us and/or by external service providers to detect and prevent threats to our systems, investigate illegal or inappropriate behavior, and/or eliminate unsolicited promotional e-mails (spam). This process could result in deletion of a legitimate e-mail before it is read by its intended recipient at our organization. Moreover, based on the scanning results, the full text of e-mails and attachments may be made available to Weatherford security and other personnel for review and appropriate action. If you have any concerns about this process, please contact us at dataprivacy@weatherford.com.

Lantz, Tracy

From: Lantz, Tracy
Sent: Tuesday, July 08, 2014 3:55 PM
To: 'Oslosky, Stanley'
Cc: Miederhoff, Eric
Subject: RE: 59106-I and 59106-O Label corrections

Generic data is the data that supports the technical active ingredient. Since you are not purchasing the active ingredient from a registered source, you must address all of the generic data requirements. This is why I previously suggested you go to the RED for glutaraldehyde. (see the link I sent last week to this RED) Here you will be able to see the data that was relied upon to support this ingredient and the uses associated with this ingredient. The uses on your label are pretty broad. I suggest you start there.

- In addition, here is the link to the list of data requirements based on the uses: http://www.epa.gov/oppfead1/cb/csb_page/updates/2013/data-require-antimicrobial.html
- Here is some general information on data compensation: <http://www.epa.gov/pesticides/bluebook/chapter10.html>
- If you decide to you the cite all method of support for any requirement, this list will be needed: <http://www.epa.gov/pesticides/DataSubmittersList/index.htm>

Tracy Lantz

Antimicrobials Division
Office of Pesticide Programs
Environmental Protection Agency
(703) 308-6415
Lantz.tracy@epa.gov

From: Oslosky, Stanley [mailto:Stanley.Oslosky@Weatherford.com]
Sent: Tuesday, July 08, 2014 2:43 PM
To: Lantz, Tracy
Subject: 59106-I and 59106-O Label corrections

Tracy,

Attached are the labels corrected and named as you have advised. Below are label with glutaraldehyde that have the some combination of the 4 uses that you have identified. [Sorry I guess I did not pick the best "me-too" product]. There are more I am sure if you need them I can do a more exhaustive search.

I hope to have the matrices to you by the end of the day, but wanted to get these to you as soon as I could.

Stan
724-316-0689

Myacide GA 50--- **Wastewater-Frac-MWF**
EPA Registration No. 33753-31

Myacide ® GA 2S--- **Wastewater-Frac-MWF—air washer etc**

EPA Registration No: 33753-26

UCARCIDETM 25 Antimicrobial—**Wastewater – Frac--MWF—air washer etc**
EPA Registration No. 464-688

UCARCIDETM 250 Antimicrobial---**Wastewater--MWF—air washer etc**
EPA Registration No. 464-691

UCARCIDE™ 45 Antimicrobial-- **Wastewater – Frac-MWF—air washer etc**
EPA Registration No 464 692

UCARCIDE™ 15 Antimicrobial-- **Wastewater – Frac-MWF—air washer etc**
EPA Registration No. 464-693

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Lantz, Tracy

From: Oslosky, Stanley <Stanley.Oslosky@Weatherford.com>
Sent: Tuesday, July 08, 2014 11:14 AM
To: Lantz, Tracy
Subject: 59106-I

Categories: Red Category

Tracy,

For an MUP/TGAI which we import. What would be the difference between the generic and the product specific matrix?

Stan
724-316-0689

From: Lantz, Tracy [mailto:Lantz.Tracy@epa.gov]
Sent: Thursday, July 03, 2014 3:47 PM
To: Oslosky, Stanley
Cc: Miederhoff, Eric
Subject: label revisions and additional information needed for 59106-I and 59106-O

Hi Stan,

Data Comp

Please correct the data matrix forms for both products. Each product should have both a product specific and a generic data matrix. The generic matrix is necessary since you are producing, not purchasing the source and thus are not able to rely on the formulator's exemption.

The product specific matrix should list the specific guideline numbers associated with the chemistry studies you submitted.

It should also list the guideline numbers for the six acute studies (primary eye, primary skin, acute dermal, acute inhalation, acute oral and dermal sensitization. You may continue to use the cite all option to support these data requirements, just list out the studies.

The generic matrix should list all of the data requirements accessed in the RED to support the uses on your label. Many of the studies used for the assessment in the RED may be old (>15 years and no longer compensable.) You can check NPRIS to determine when each study was submitted. Alternately, you can use the cite all method of support. Either way, please list the data requirements by guideline number.

Here is the link to the glutaraldehyde RED: <http://www.epa.gov/oppsrrd1/REDs/glutaraldehyde-red.pdf>

Please revise your public file copy of each form to be in agreement with each new matrix.

Labeling

Please revise both labels to list the appropriate registration numbers: 59106-8 for the MUP and 59106-9 for the end use product.

Please revise the environmental hazards statement for both labels to be in agreement with the gluteraldehyde RED as follows: (page 67)

"This product is toxic to fish, aquatic invertebrates, oysters and shrimp. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."

Add the following statement to the end use product, 59106-O (also per the RED):

Additional PPE "long-sleeve shirt, long pants, shoes, socks, chemical-resistant gloves, and chemical-resistant apron"

Please prepare these in the same electronic format as you provided last night, but it would be helpful if you used our naming scheme: 059106-00008.20140703.whatever you want here.pdf (Of course revise the product number for each and use the date that you complete work on the file.)

I have not finished my review of the end use product label, but wanted to get the above comments to you now.
I should finish that label soon, probably by the end of the day.

I do not have the final chemistry review for these products so do not know if there are any concerns at this time.

Thanks in advance,

Tracy Lantz

Antimicrobials Division
Office of Pesticide Programs
Environmental Protection Agency
(703) 308-6415
Lantz.tracy@epa.gov

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Verizon Message Center

Thursday, Jul 3 at 3:54 PM

From: "Lantz, Tracy" <Lantz.Tracy@epa.gov>

To: [REDACTED]

Subject: FW: label revisions and additional information needed for 59106-I and 59106-O

Tracy Lantz

Antimicrobials Division
Office of Pesticide Programs
Environmental Protection Agency
(703) 308-6415
Lantz.tracy@epa.gov

Both Products

From: Lantz, Tracy

Sent: Thursday, July 03, 2014 3:47 PM

To: 'Oslosky, Stanley'

Cc: Miederhoff, Eric

Subject: label revisions and additional information needed for 59106-I and 59106-O

Hi Stan,

Data Comp

Please correct the data matrix forms for both products. Each product should have both a product specific and a generic data matrix. The generic matrix is necessary since you are producing, not purchasing the source and thus are not able to rely on the formulator's exemption.

The product specific matrix should list the specific guideline numbers associated with the chemistry studies you submitted.

It should also list the guideline numbers for the six acute studies (primary eye, primary skin, acute dermal, acute inhalation, acute oral and dermal sensitization. You may continue to use the cite all option to support these data requirements, just list out the studies.

The generic matrix should list all of the data requirements accessed in the RED to support the uses on your label. Many of the studies used for the assessment in the RED may be old (>15 years and no longer compensable.) You can check NPRIS to determine when each study was submitted. Alternately, you can use the cite all method of support. Either way, please list the data requirements by guideline number.

Here is the link to the glutaraldehyde RED: <http://www.epa.gov/oppsrrd1/REDs/glutaraldehyde-red.pdf>

Please revise your public file copy of each form to be in agreement with each new matrix.

Labeling

Please revise both labels to list the appropriate registration numbers: 59106-8 for the MUP and 59106-9 for the end use product.

Please revise the environmental hazards statement for both labels to be in agreement with the glutaraldehyde RED as follows: (page 67)

Personal privacy information

"This product is toxic to fish, aquatic invertebrates, oysters and shrimp. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."

Add the following statement to the end use product, 59106-O (also per the RED):

Additional PPE "long-sleeve shirt, long pants, shoes, socks, chemical-resistant gloves, and chemical-resistant apron"

Please prepare these in the same electronic format as you provided last night, but it would be helpful if you used our naming scheme: 059106-00008.20140703.whatever you want here.pdf (Of course revise the product number for each and use the date that you complete work on the file.)

I have not finished my review of the end use product label, but wanted to get the above comments to you now.
I should finish that label soon, probably by the end of the day.
I do not have the final chemistry review for these products so do not know if there are any concerns at this time.

Thanks in advance.

Tracy Lantz
Antimicrobials Division
Office of Pesticide Programs
Environmental Protection Agency
(703) 308-6415
Lantz.tracy@epa.gov

Lantz, Tracy

From: Oslosky, Stanley <Stanley.Oslosky@Weatherford.com>
Sent: Tuesday, July 08, 2014 4:55 PM
To: Lantz, Tracy
Subject: RE: 59106-I
Attachments: 059106-00008-20140703_Bioclear G50--Generic matrix.pdf; 059106-00008-20140703_Bioclear G50--Generic matrix_masked.pdf; 059106-00008--20140703_Product Specific masked.pdf; 059106-00008--20140703_Product Specific matrix.pdf

Categories: PRINT THIS

Tracy,
Here are the matrices for 59106-I. 59106-O's will follow shortly as soon as I can mask them.

Stan

From: Lantz, Tracy [mailto:Lantz.Tracy@epa.gov]
Sent: Tuesday, July 08, 2014 4:07 PM
To: Oslosky, Stanley
Subject: RE: 59106-I and 59106-O Label corrections

Since you are submitting some of your own data to address these requirements (chemistry) and are using cite all to support other requirements, you need to be more specific with the exact guidelines for which you are offering to pay compensation. "870.xxx Toxicology" " 850.xxx Antimicrobial Nontarget organism" etc., is not sufficient.

Tracy Lantz

Antimicrobials Division
Office of Pesticide Programs
Environmental Protection Agency
(703) 308-6415
Lantz.tracy@epa.gov

From: Oslosky, Stanley [mailto:Stanley.Oslosky@Weatherford.com]
Sent: Tuesday, July 08, 2014 3:59 PM
To: Lantz, Tracy
Subject: RE: 59106-I and 59106-O Label corrections

Tracy,

I previously provided matrices that indicated that for certain data requirements, other than chemistry, that I wanted to use the cite-all method. I also provided with my submission a list of those submitters to whom I send offers-to-pay. Do you not have these documents?

Stan

From: Lantz, Tracy [mailto:Lantz.Tracy@epa.gov]
Sent: Tuesday, July 08, 2014 3:55 PM
To: Oslosky, Stanley

Cc: Miederhoff, Eric
Subject: RE: 59106-I and 59106-O Label corrections

Generic data is the data that supports the technical active ingredient. Since you are not purchasing the active ingredient from a registered source, you must address all of the generic data requirements. This is why I previously suggested you go to the RED for glutaraldehyde. (see the link I sent last week to this RED) Here you will be able to see the data that was relied upon to support this ingredient and the uses associated with this ingredient. The uses on your label are pretty broad. I suggest you start there.

- In addition, here is the link to the list of data requirements based on the uses: http://www.epa.gov/oppfead1/cb/csb_page/updates/2013/data-require-antimicrobial.html
- Here is some general information on data compensation: <http://www.epa.gov/pesticides/bluebook/chapter10.html>
- If you decide to you the cite all method of support for any requirement, this list will be needed: <http://www.epa.gov/pesticides/DataSubmittersList/index.htm>

Tracy Lantz

Antimicrobials Division
Office of Pesticide Programs
Environmental Protection Agency
(703) 308-6415
Lantz.tracy@epa.gov

From: Oslosky, Stanley [<mailto:Stanley.Oslosky@Weatherford.com>]
Sent: Tuesday, July 08, 2014 2:43 PM
To: Lantz, Tracy
Subject: 59106-I and 59106-O Label corrections

Tracy,

Attached are the labels corrected and named as you have advised. Below are label with glutaraldehyde that have the some combination of the 4 uses that you have identified. [Sorry I guess I did not pick the best "me-too" product]. There are more I am sure if you need them I can do a more exhaustive search.

I hope to have the matrices to you by the end of the day, but wanted to get these to you as soon as I could.

Stan
724-316-0689

Myacide GA 50--- **Wastewater-Frac-MWF**
EPA Registration No. 33753-31

Myacide ® GA 2S--- **Wastewater-Frac-MWF—air washer etc**
EPA Registration No: 33753-26

UCARCIDETM 25 Antimicrobial—**Wastewater – Frac--MWF—air washer etc**
EPA Registration No. 464-688

UCARCIDETM 250 Antimicrobial---**Wastewater--MWF—air washer etc**
EPA Registration No. 464-691

UCARCIDE™ 45 Antimicrobial-- **Wastewater – Frac-MWF—air washer etc**
EPA Registration No 464 692

UCARCIDE™ 15 Antimicrobial-- **Wastewater – Frac-MWF—air washer etc**
EPA Registration No. 464-693

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

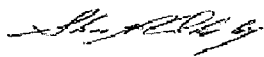
Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registrations and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

DATA MATRIX-(Generic)

Date January 27, 2014	EPA Reg. No./File Symbol 59106-I	Page 1 of 6
Applicant's/Registrant's Name & Address CLEARWATER INTERNATIONAL LLC, D/B/A WEATHERFORD ENGINEERED CHEMISTRY, HOUSTON, TX 77056		Product: BioClear G50

Ingredients Glutaraldehyde

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Product Chemistry		59106	OWN	Vol. 1
830.1550	Product identity and composition	49310101/49375201	59106	OWN	Vol. 1
830.1600	Description of starting materials	49310101	59106	OWN	Vol. 1
830.1620	Description of production process	49310101	59106	OWN	Vol. 1
830.1670	Discussion of formation of impurities	49310101	59106	OWN	Vol. 1
830.1700	Preliminary Analysis of Product	49310102	59106	OWN	Vol. 1
830.1750	Certification of limits	49310101	59106	OWN	Vol. 2
830.1800	Enforcement Analytical methods	49310101	59106	OWN	Vol. 1
830.1900	Submittal of Samples	On request	59106	OWN	Vol. 1
830.6302	Color	49310103	59106	OWN	Vol. 3
830.6303	Physical State	49310103	59106	OWN	Vol. 3
830.6304	Odor	49310103	59106	OWN	Vol. 3
830.6313	Stability –Temperature Stability	49310103	59106	OWN	Vol. 3
830.6313	Stability –Metal Ions	49310105/49375202	59106	OWN	Waiver Vol. 5
830.6314	Oxidizing/reducing reaction	49310105/49375202	59106	OWN	Waiver Vol. 5
830.6315	Flammability	49310105/49375202	59106	OWN	Waiver Vol. 5
830.6316	Explosability	49310105/49375202	59106	OWN	Waiver Vol. 5

Signature 	Name and Title Stan Oslosky, Consultant to Weatherford	Date 7/7/14
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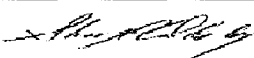


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DATA MATRIX-(Generic)

Date January 27, 2014			EPA Reg. No./File Symbol 59106-I		Page 2 of 6
Applicant's/Registrant's Name & Address CLEARWATER INTERNATIONAL LLC, D/B/A WEATHERFORD ENGINEERED CHEMISTRY, HOUSTON, TX 77056			Product: BioClear G50		
Ingredients Glutaraldehyde					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6317	Storage stability	49310105/49375202	59106 (provide when done)	OWN	Waiver Vol. 5
830.6319	Miscibility	49310105/49375202	59106	OWN	Waiver Vol. 5
830.6320	Corrosion Characteristics	49310105/49375202	59106 (provide when done)	OWN	Waiver Vol. 5
830.6321	Dielectric breakdown voltage	49310105/49375202	59106	OWN	Waiver Vol. 5
830.7000	pH	49310103	59106	OWN	Vol. 3
830.7100	Viscosity	49379501	39967	OWN	
830.7220	Boiling Point	49310103	59106	OWN	Vol. 3
830.7300	Density	49310103	59106	OWN	Vol. 3
830.7370	Dissociation Constant	49310105/49375202	59106	OWN	Waiver Vol. 5
830.7550	Octanol/Water Partition Coefficient	49310103	59106	OWN	Vol. 3
830.7840	Solubility – Water	49310103	59106	OWN	Vol. 3
830.7950	Vapor Pressure	49310103	59106	OWN	Vol. 4
Signature 			Name and Title Stan Oslosky, Consultant to Weatherford		Date 7/7/14



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DATA MATRIX-(Generic)

Date January 27, 2014	EPA Reg. No./File Symbol 59106-I	Page 3 of 6
Applicant's/Registrant's Name & Address CLEARWATER INTERNATIONAL LLC, D/B/A WEATHERFORD ENGINEERED CHEMISTRY, HOUSTON, TX 77056		Product: BioClear G50

Ingredients Glutaraldehyde

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.2100	Avian Acute Oral Toxicity -Duck	117070	662	old	
850.2100	Avian Acute Oral Toxicity -Duck	164373	662	old	
850.1010	Freshwater Invertebrate Acute Toxicology	43645701	10352 (464)	old	
850.1010	Freshwater Invertebrate Acute Toxicology	117075	7969	old	
850.1010	Freshwater Invertebrate Acute Toxicology	125516	10352 (464)	old	
850.1010	Freshwater Invertebrate Acute Toxicology	42110101	10352 (464)	old	
850.1075	Freshwater Fish Acute Toxicology	125515	10352 (464)	old	
850.1075	Freshwater Fish Acute Toxicology	117077	7969	old	
850.1075	Freshwater Fish Acute Toxicology	117076	662	old	
850.1075	Freshwater Fish Acute Toxicology	42612102	65864	old	
850.1025	Acute Toxicity- Sheepshead Minnow	42753201	10352 (464)	old	
850.1025	Acute Toxicity- Sheepshead Minnow	117074	662	old	
850.1025	Acute Toxicity-Mysid Shrimp	42952301	10352 (464)	old	
850.1025	Acute Toxicity-Eastern Oyster	42952101	10352 (464)	old	
850.1500	Fish early-life	46373901	33573	pay	
850.2200	Avian Subacute Dietary-Mallard duck	117071	662	old	

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Applicant's/Registrant's Name & Address CLEARWATER INTERNATIONAL LLC, D/B/A WEATHERFORD ENGINEERED CHEMISTRY, HOUSTON, TX 77056	Product: BioClear G50	

Ingredients Glutaraldehyde

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.2200	Avian Subacute Dietary-Mallard duck	125519	10352 (464)	old	
850.2200	Avian Subacute Dietary-Quail	42110601	10352 (464)	old	
850.2200	Avian Subacute Dietary-Quail	42110401	10352 (464)	old	
850.2200	Avian Subacute Dietary-Quail	117072	662	old	
850.2200	Avian Subacute Dietary-Quail	125520	10352 (464)	old	
850.5400	Aquatic plant growth	44289002	10352 (464)	old	
850.5400	Aquatic plant growth	45609401	464	pay	
870.xxx	Toxicology				
870.1100	Acute oral LD-50	11706	662	old	
870.1100	Acute oral LD-50	164370	662	old	
870.1200	Acute dermal LD-50	44691606	33753	old	
870.1300	Acute inhalation LC-50	60275	5009	old	
870.2400	Primary eye irritation	117066	662	old	
870.2500	Primary skin irritation	117063	662	old	
870.2600	Skin sensitization	43330201	10352(464)	old	
870.3100	14-Day oral toxicity—mice (range finder)	40908101	10352(464)	old	
870.3100	90- Day oral toxicity—mice	41089601	10352(464)	old	

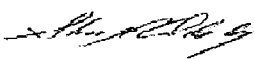
Signature 	Name and Title Stan Oslosky, Consultant to Weatherford	Date 7/7/14
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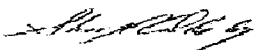
Date January 27, 2014		EPA Reg. No./File Symbol 59106-I		Page 5 of 6	
Applicant's/Registrant's Name & Address CLEARWATER INTERNATIONAL LLC, D/B/A WEATHERFORD ENGINEERED CHEMISTRY, HOUSTON, TX 77056		Product: BioClear G50			
Ingredients Glutaraldehyde					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.3150	90- Day oral toxicity—dog	41480501	10352(464)	old	
870.3100	Subchronic Oral Toxicity and Neurotoxicity	46046802	10352(464)	pay	
870.3200	28-Day dermal toxicity	43259101	10352(464)	old	
870.3250	90-Day dermal toxicity	46046802	33753	pay	
870.3400	14-day inhalation study	164178	10352(464)	old	
870.3450	90-day inhalation study	42911801	10352(464)	old	
870.4100	Chronic Toxicity Study-rat	46046804	33753	pay	
870.4100	Chronic Toxicity Study-dog	46624901	33753	pay	
870.4100	Chronic Inhalation Rats and mice	45082401	10352(464)	pl	
870.4100	Chronic Inhalation Rats and mice	45250301	10352(464)	pl	
870.3700	Prenatal Toxicity-Rabbit	42154001	10352(464)	old	
870.3700	Prenatal Toxicity-Rat	42154101	10352(464)	old	
870.6300	Two-Generation Reproduction Study-rat	43189701	10352(464)	old	
870.5100	Reverse mutation assay	164186	10352(464)	old	
870.5100	Reverse mutation assay	164456	10352(464)	old	
870.5100	Reverse mutation assay	164457	10352(464)	pl	
870.5100	Reverse mutation assay	164458	10352(464)	old	
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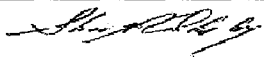
Date January 27, 2014		EPA Reg. No./File Symbol 59106-I		Page 6 of 6	
Applicant's/Registrant's Name & Address CLEARWATER INTERNATIONAL LLC, D/B/A WEATHERFORD ENGINEERED CHEMISTRY, HOUSTON, TX 77056		Product: BioClear G50			
Ingredients Glutaraldehyde					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.5100	Reverse mutation assay	43010201	10352(464)	old	
870.5100	Reverse mutation assay	43211601	10352(464)	old	
870.5300	<i>In vitro</i> mammalian	42035301	10352(464)	old	
870.5300	<i>In vitro</i> mammalian	42129201	10352(464)	old	
870.5300	<i>In vitro</i> mammalian	42851701	10352(464)	old	
870.5300	<i>In vitro</i> mammalian	43204201	10352(464)	old	
870.5395	<i>In vivo</i> cytogenetics	43213401	10352(464)	old	
870.5385	<i>In vivo</i> cytogenetics	42707301	10352(464)	old	
875.1100	Dermal exposure		AEATF II member (data being developed)	own	
875.1300	Inhalation Exposure		AEATF II member (data being developed)	own	
875.1600	Data reporting and calculations		AEATF II member (data being developed)	own	
875.1700	Product use information		AEATF II member (data being developed)	own	
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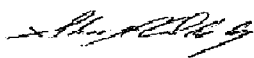
Date January 27, 2014		EPA Reg. No./File Symbol 59106-l		Page 1 of 6	
Applicant's/Registrant's Name & Address CLEARWATER INTERNATIONAL LLC, D/B/A WEATHERFORD ENGINEERED CHEMISTRY, HOUSTON, TX 77056		Product: BioClear G50			
Ingredients Glutaraldehyde					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			59106	OWN	Vol. 1
			59106	OWN	Vol. 1
			59106	OWN	Vol. 1
			59106	OWN	Vol. 1
			59106	OWN	Vol. 1
			59106	OWN	Vol. 1
			59106	OWN	Vol. 2
			59106	OWN	Vol. 1
			59106	OWN	Vol. 1
			59106	OWN	Vol. 3
			59106	OWN	Vol. 3
			59106	OWN	Vol. 3
			59106	OWN	Vol. 3
			59106	OWN	Waiver Vol. 5
			59106	OWN	Waiver Vol. 5
			59106	OWN	Waiver Vol. 5
			59106	OWN	Waiver Vol. 5
			Signature 		



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Date January 27, 2014		EPA Reg. No./File Symbol 59106-I		Page 2 of 6	
Applicant's/Registrant's Name & Address CLEARWATER INTERNATIONAL LLC, D/B/A WEATHERFORD ENGINEERED CHEMISTRY, HOUSTON, TX 77056		Product: BioClear G50			
Ingredients Glutaraldehyde					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			59106 (provide when done)	OWN	Waiver Vol. 5
			59106	OWN	Waiver Vol. 5
			59106 (provide when done)	OWN	Waiver Vol. 5
			59106	OWN	Waiver Vol. 5
			59106	OWN	Vol. 3
			39967	OWN	
			59106	OWN	Vol. 3
			59106	OWN	Vol. 3
			59106	OWN	Waiver Vol. 5
			59106	OWN	Vol. 3
			59106	OWN	Vol. 3
			59106	OWN	Vol. 4
Signature 			Name and Title Stan Oslosky, Consultant to Weatherford		Date 7/7/14



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DATA MATRIX-(Generic)

Date January 27, 2014 EPA Reg. No./File Symbol 59106-I Page 3 of 6

Applicant's/Registrant's Name & Address
CLEARWATER INTERNATIONAL LLC, D/B/A WEATHERFORD ENGINEERED CHEMISTRY,
HOUSTON, TX 77056

Product: BioClear G50

Ingredients Glutaraldehyde

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			662	old	
			662	old	
			10352 (464)	old	
			7969	old	
			10352 (464)	old	
			10352 (464)	old	
			10352 (464)	old	
			7969	old	
			662	old	
			65864	old	
			10352 (464)	old	
			662	old	
			10352 (464)	old	
			10352 (464)	old	
			33573	pay	
			662	old	

Signature

Name and Title
Stan Oslosky, Consultant to Weatherford

Date
7/7/14



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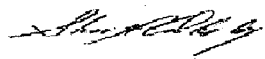
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Date January 27, 2014	EPA Reg. No./File Symbol 59106-I	Page 4 of 6
Applicant's/Registrant's Name & Address CLEARWATER INTERNATIONAL LLC, D/B/A WEATHERFORD ENGINEERED CHEMISTRY, HOUSTON, TX 77056	Product: BioClear G50	

Ingredients Glutaraldehyde

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.2200	Avian Subacute Dietary Mallard duck	125519	10352 (464)	old	
			10352 (464)	old	
			10352 (464)	old	
			662	old	
			10352 (464)	old	
			10352 (464)	old	
			464	pay	
			662	old	
			662	old	
			33753	old	
			5009	old	
			662	old	
			662	old	
			10352(464)	old	
			10352(464)	old	
			10352(464)	old	

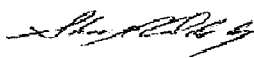
Signature 	Name and Title Stan Oslosky, Consultant to Weatherford	Date 7/7/14
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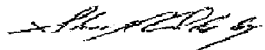
Date January 27, 2014		EPA Reg. No./File Symbol 59106-I		Page 5 of 6			
Applicant's/Registrant's Name & Address CLEARWATER INTERNATIONAL LLC, D/B/A WEATHERFORD ENGINEERED CHEMISTRY, HOUSTON, TX 77056		Product: BioClear G50					
Ingredients Glutaraldehyde							
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note		
			10352(464)	old			
			10352(464)	pay			
			10352(464)	old			
			33753	pay			
			10352(464)	old			
			10352(464)	old			
			33753	pay			
			33753	pay			
			10352(464)	pl			
			10352(464)	pl			
			10352(464)	old			
			10352(464)	old			
			10352(464)	old			
			10352(464)	old			
			10352(464)	pl			
			10352(464)	old			
			Signature 		Name and Title Stan Oslosky, Consultant to Weatherford		Date 7/7/14



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Date January 27, 2014		EPA Reg. No./File Symbol 59106-I		Page 6 of 6	
Applicant's/Registrant's Name & Address CLEARWATER INTERNATIONAL LLC, D/B/A WEATHERFORD ENGINEERED CHEMISTRY, HOUSTON, TX 77056		Product: BioClear G50			
Ingredients Glutaraldehyde					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			10352(464)	old	
			10352(464)	old	
			10352(464)	old	
			10352(464)	old	
			10352(464)	old	
			10352(464)	old	
			10352(464)	old	
			10352(464)	old	
			10352(464)	old	
			AEATF II member (data being developed)	own	
			AEATF II member (data being developed)	own	
			AEATF II member (data being developed)	own	
			AEATF II member (data being developed)	own	
Signature 			Name and Title Stan Oslosky, Consultant to Weatherford		Date 7/7/14



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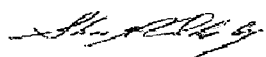
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DATA MATRIX---(Product Specific)

Date January 27, 2014	EPA Reg. No./File Symbol 59106-I	Page 1 of 6
Applicant's/Registrant's Name & Address CLEARWATER INTERNATIONAL LLC, D/B/A WEATHERFORD ENGINEERED CHEMISTRY, HOUSTON, TX 77056		Product: BioClear G50

Ingredients Glutaraldehyde

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Product Chemistry		59106	OWN	Vol. 1
830.1550	Product identity and composition	49310101/49375201	59106	OWN	Vol. 1
830.1600	Description of starting materials	49310101	59106	OWN	Vol. 1
830.1620	Description of production process	49310101	59106	OWN	Vol. 1
830.1670	Discussion of formation of impurities	49310101	59106	OWN	Vol. 1
830.1700	Preliminary Analysis of Product	49310102	59106	OWN	Vol. 1
830.1750	Certification of limits	49310101	59106	OWN	Vol. 2
830.1800	Enforcement Analytical methods	49310101	59106	OWN	Vol. 1
830.1900	Submittal of Samples	On request	59106	OWN	Vol. 1
830.6302	Color	49310103	59106	OWN	Vol. 3
830.6303	Physical State	49310103	59106	OWN	Vol. 3
830.6304	Odor	49310103	59106	OWN	Vol. 3
830.6313	Stability –Temperature Stability	49310103	59106	OWN	Vol. 3
830.6313	Stability –Metal Ions	49310105/49375202	59106	OWN	Waiver Vol. 5
830.6314	Oxidizing/reducing reaction	49310105/49375202	59106	OWN	Waiver Vol. 5
830.6315	Flammability	49310105/49375202	59106	OWN	Waiver Vol. 5
830.6316	Explosibility	49310105/49375202	59106	OWN	Waiver Vol. 5

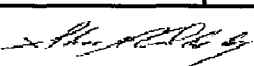
Signature 	Name and Title Stan Oslosky, Consultant to Weatherford	Date 7/7/14
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DATA MATRIX--(Product Specific)

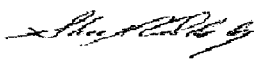
Date January 27, 2014		EPA Reg. No./File Symbol 59106-I		Page 2 of 6	
Applicant's/Registrant's Name & Address CLEARWATER INTERNATIONAL LLC, D/B/A WEATHERFORD ENGINEERED CHEMISTRY, HOUSTON, TX 77056		Product: BioClear G50			
Ingredients Glutaraldehyde					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6317	Storage stability	49310105/49375202	59106 (provide when done)	OWN	Waiver Vol. 5
830.6319	Miscibility	49310105/49375202	59106	OWN	Waiver Vol. 5
830.6320	Corrosion Characteristics	49310105/49375202	59106 (provide when done)	OWN	Waiver Vol. 5
830.6321	Dielectric breakdown voltage	49310105/49375202	59106	OWN	Waiver Vol. 5
830.7000	pH	49310103	59106	OWN	Vol. 3
830.7100	Viscosity	49379501	39967	OWN	
830.7220	Boiling Point	49310103	59106	OWN	Vol. 3
830.7300	Density	49310103	59106	OWN	Vol. 3
830.7370	Dissociation Constant	49310105/49375202	59106	OWN	Waiver Vol. 5
830.7550	Octanol/Water Partition Coefficient	49310103	59106	OWN	Vol. 3
830.7840	Solubility – Water	49310103	59106	OWN	Vol. 3
830.7950	Vapor Pressure	49310103	59106	OWN	Vol. 4
Signature 			Name and Title Stan Oslosky, Consultant to Weatherford		Date 7/7/14



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DATA MATRIX--(Product Specific)

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Applicant's/Registrant's Name & Address CLEARWATER INTERNATIONAL LLC, D/B/A WEATHERFORD ENGINEERED CHEMISTRY, HOUSTON, TX 77056		Product: BioClear G50			
Ingredients Glutaraldehyde					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.2100	Avian Acute Oral Toxicity -Duck	117070	662	old	
850.2100	Avian Acute Oral Toxicity -Duck	164373	662	old	
850.1010	Freshwater Invertebrate Acute Toxicology	43645701	10352 (464)	old	
850.1010	Freshwater Invertebrate Acute Toxicology	117075	7969	old	
850.1010	Freshwater Invertebrate Acute Toxicology	125516	10352 (464)	old	
850.1010	Freshwater Invertebrate Acute Toxicology	42110101	10352 (464)	old	
850.1075	Freshwater Fish Acute Toxicology	125515	10352 (464)	old	
850.1075	Freshwater Fish Acute Toxicology	117077	7969	old	
850.1075	Freshwater Fish Acute Toxicology	117076	662	old	
850.1075	Freshwater Fish Acute Toxicology	42612102	65864	old	
850.1025	Acute Toxicity- Sheepshead Minnow	42753201	10352 (464)	old	
850.1025	Acute Toxicity- Sheepshead Minnow	117074	662	old	
850.1025	Acute Toxicity-Mysid Shrimp	42952301	10352 (464)	old	
850.1025	Acute Toxicity-Eastern Oyster	42952101	10352 (464)	old	
850.1500	Fish early-life	46373901	33573	pay	
850.2200	Avian Subacute Dietary-Mallard duck	117071	662	old	
Signature 		Name and Title Stan Oslosky, Consultant to Weatherford			Date 7/7/14



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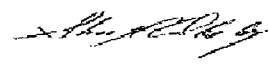
Date January 27, 2014 EPA Reg. No./File Symbol 59106-I Page 4 of 6

Applicant's/Registrant's Name & Address
CLEARWATER INTERNATIONAL LLC, D/B/A WEATHERFORD ENGINEERED CHEMISTRY,
HOUSTON, TX 77056

Product: BioClear G50

Ingredients Glutaraldehyde

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.2200	Avian Subacute Dietary-Mallard duck	125519	10352 (464)	old	
850.2200	Avian Subacute Dietary-Quail	42110601	10352 (464)	old	
850.2200	Avian Subacute Dietary-Quail	42110401	10352 (464)	old	
850.2200	Avian Subacute Dietary-Quail	117072	662	old	
850.2200	Avian Subacute Dietary-Quail	125520	10352 (464)	old	
850.5400	Aquatic plant growth	44289002	10352 (464)	old	
850.5400	Aquatic plant growth	45609401	464	pay	
870.xxx	Toxicology				
870.1100	Acute oral LD-50	11706	662	old	
870.1100	Acute oral LD-50	164370	662	old	
870.1200	Acute dermal LD-50	44691606	33753	old	
870.1300	Acute inhalation LC-50	60275	5009	old	
870.2400	Primary eye irritation	117066	662	old	
870.2500	Primary skin irritation	117063	662	old	
870.2600	Skin sensitization	43330201	10352(464)	old	
870.3100	14-Day oral toxicity—mice (range finder)	40908101	10352(464)	old	
870.3100	90- Day oral toxicity—mice	41089601	10352(464)	old	

Signature 

Name and Title
Stan Oslosky, Consultant to Weatherford

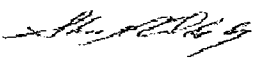
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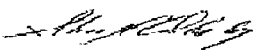
Date January 27, 2014			EPA Reg. No./File Symbol 59106-I		Page 5 of 6
Applicant's/Registrant's Name & Address CLEARWATER INTERNATIONAL LLC, D/B/A WEATHERFORD ENGINEERED CHEMISTRY, HOUSTON, TX 77056			Product: BioClear G50		
Ingredients Glutaraldehyde					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.3150	90- Day oral toxicity—dog	41480501	10352(464)	old	
870.3100	Subchronic Oral Toxicity and Neurotoxicity	46046802	10352(464)	pay	
870.3200	28-Day dermal toxicity	43259101	10352(464)	old	
870.3250	90-Day dermal toxicity	46046802	33753	pay	
870.3400	14-day inhalation study	164178	10352(464)	old	
870.3450	90-day inhalation study	42911801	10352(464)	old	
870.4100	Chronic Toxicity Study-rat	46046804	33753	pay	
870.4100	Chronic Toxicity Study-dog	46624901	33753	pay	
870.4100	Chronic Inhalation Rats and mice	45082401	10352(464)	pl	
870.4100	Chronic Inhalation Rats and mice	45250301	10352(464)	pl	
870.3700	Prenatal Toxicity-Rabbit	42154001	10352(464)	old	
870.3700	Prenatal Toxicity-Rat	42154101	10352(464)	old	
870.6300	Two-Generation Reproduction Study-rat	43189701	10352(464)	old	
870.5100	Reverse mutation assay	164186	10352(464)	old	
870.5100	Reverse mutation assay	164456	10352(464)	old	
870.5100	Reverse mutation assay	164457	10352(464)	pl	
870.5100	Reverse mutation assay	164458	10352(464)	old	
Signature 			Name and Title Stan Oslosky, Consultant to Weatherford		Date 7/7/14



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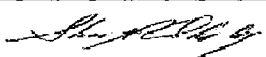
Date January 27, 2014		EPA Reg. No./File Symbol 59106-I		Page 6 of 6	
Applicant's/Registrant's Name & Address CLEARWATER INTERNATIONAL LLC, D/B/A WEATHERFORD ENGINEERED CHEMISTRY, HOUSTON, TX 77056		Product: BioClear G50			
Ingredients Glutaraldehyde					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.5100	Reverse mutation assay	43010201	10352(464)	old	
870.5100	Reverse mutation assay	43211601	10352(464)	old	
870.5300	<i>In vitro</i> mammalian	42035301	10352(464)	old	
870.5300	<i>In vitro</i> mammalian	42129201	10352(464)	old	
870.5300	<i>In vitro</i> mammalian	42851701	10352(464)	old	
870.5300	<i>In vitro</i> mammalian	43204201	10352(464)	old	
870.5395	<i>In vivo</i> cytogenetics	43213401	10352(464)	old	
870.5385	<i>In vivo</i> cytogenetics	42707301	10352(464)	old	
875.1100	Dermal exposure		AEATF II member (data being developed)	own	
875.1300	Inhalation Exposure		AEATF II member (data being developed)	own	
875.1600	Data reporting and calculations		AEATF II member (data being developed)	own	
875.1700	Product use information		AEATF II member (data being developed)	own	
Signature 			Name and Title Stan Oslosky, Consultant to Weatherford		Date 7/7/14



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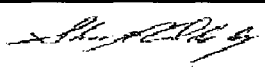
Date January 27, 2014		EPA Reg. No./File Symbol 59106-I		Page 1 of 6	
Applicant's/Registrant's Name & Address CLEARWATER INTERNATIONAL LLC, D/B/A WEATHERFORD ENGINEERED CHEMISTRY, HOUSTON, TX 77056		Product: BioClear G50			
Ingredients Glutaraldehyde					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			59106	OWN	Vol. 1
			59106	OWN	Vol. 1
			59106	OWN	Vol. 1
			59106	OWN	Vol. 1
			59106	OWN	Vol. 1
			59106	OWN	Vol. 1
			59106	OWN	Vol. 2
			59106	OWN	Vol. 1
			59106	OWN	Vol. 1
			59106	OWN	Vol. 3
			59106	OWN	Vol. 3
			59106	OWN	Vol. 3
			59106	OWN	Vol. 3
			59106	OWN	Waiver Vol. 5
			59106	OWN	Waiver Vol. 5
			59106	OWN	Waiver Vol. 5
			59106	OWN	Waiver Vol. 5
			Signature 		



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Date January 27, 2014		EPA Reg. No./File Symbol 59106-I		Page 2 of 6	
Applicant's/Registrant's Name & Address CLEARWATER INTERNATIONAL LLC, D/B/A WEATHERFORD ENGINEERED CHEMISTRY, HOUSTON, TX 77056		Product: BioClear G50			
Ingredients Glutaraldehyde					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			59106 (provide when done)	OWN	Waiver Vol. 5
			59106	OWN	Waiver Vol. 5
			59106 (provide when done)	OWN	Waiver Vol. 5
			59106	OWN	Waiver Vol. 5
			59106	OWN	Vol. 3
			39967	OWN	
			59106	OWN	Vol. 3
			59106	OWN	Vol. 3
			59106	OWN	Waiver Vol. 5
			59106	OWN	Vol. 3
			59106	OWN	Vol. 3
			59106	OWN	Vol. 4
Signature 			Name and Title Stan Oslosky, Consultant to Weatherford		Date 7/7/14



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Date January 27, 2014 EPA Reg. No./File Symbol 59106-I Page 3 of 6

Applicant's/Registrant's Name & Address

CLEARWATER INTERNATIONAL LLC, D/B/A WEATHERFORD ENGINEERED CHEMISTRY,
HOUSTON, TX 77056

Product: BioClear G50

Ingredients Glutaraldehyde

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			662	old	
			662	old	
			10352 (464)	old	
			7969	old	
			10352 (464)	old	
			10352 (464)	old	
			10352 (464)	old	
			7969	old	
			662	old	
			65864	old	
			10352 (464)	old	
			662	old	
			10352 (464)	old	
			10352 (464)	old	
			33573	pay	
			662	old	

Signature

Name and Title

Stan Oslosky, Consultant to Weatherford

Date

7/7/14



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DATA MATRIX--(Product Specific)

Date January 27, 2014 EPA Reg. No./File Symbol 59106-I Page 4 of 6

Applicant's/Registrant's Name & Address
CLEARWATER INTERNATIONAL LLC, D/B/A WEATHERFORD ENGINEERED CHEMISTRY,
HOUSTON, TX 77056

Product: BioClear G50

Ingredients Glutaraldehyde

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			10352 (464)	old	
			10352 (464)	old	
			10352 (464)	old	
			662	old	
			10352 (464)	old	
			10352 (464)	old	
			464	pay	
			662	old	
			662	old	
			33753	old	
			5009	old	
			662	old	
			662	old	
			10352(464)	old	
			10352(464)	old	
			10352(464)	old	

Signature

Name and Title

Stan Oslosky, Consultant to Weatherford

Date
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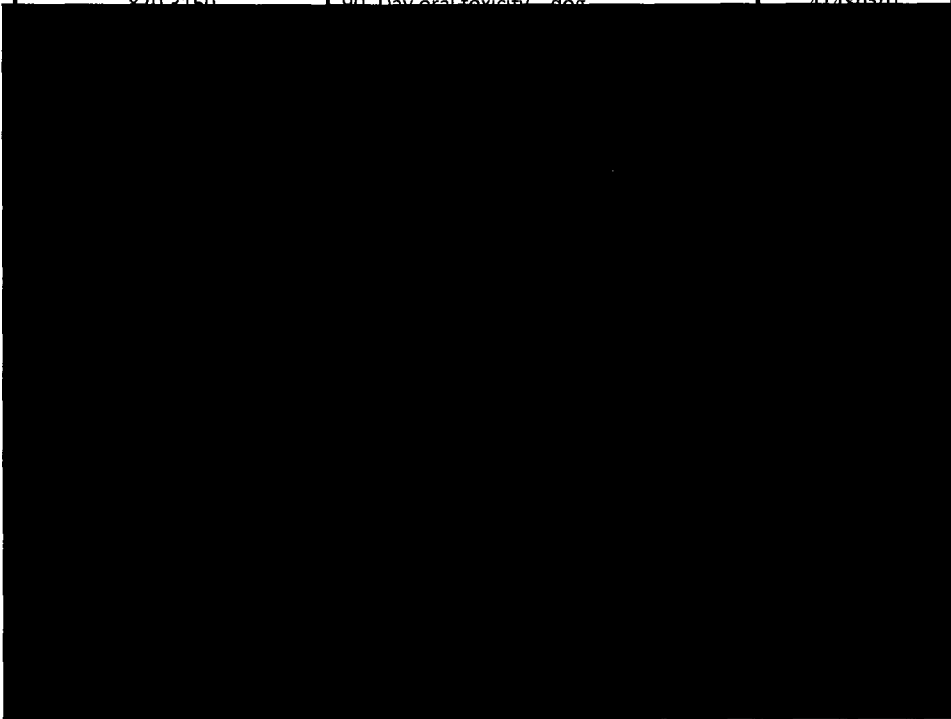
DATA MATRIX--(Product Specific)

Date January 27, 2014 EPA Reg. No./File Symbol 59106-I Page 5 of 6

Applicant's/Registrant's Name & Address
CLEARWATER INTERNATIONAL LLC, D/B/A WEATHERFORD ENGINEERED CHEMISTRY,
HOUSTON, TX 77056

Product: BioClear G50

Ingredients Glutaraldehyde

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870-2150	90-Day oral toxicity, dog	41480501	10352(464)	old	
			10352(464)	pay	
			10352(464)	old	
			33753	pay	
			10352(464)	old	
			10352(464)	old	
			33753	pay	
			33753	pay	
			10352(464)	pl	
			10352(464)	pl	
			10352(464)	old	
			10352(464)	old	
			10352(464)	old	
			10352(464)	old	
			10352(464)	old	
			10352(464)	pl	
			10352(464)	old	

Name and Title

Stan Oslosky, Consultant to Weatherford

Date
7/7/14

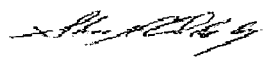
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Applicant's/Registrant's Name & Address CLEARWATER INTERNATIONAL LLC, D/B/A WEATHERFORD ENGINEERED CHEMISTRY, HOUSTON, TX 77056		Product: BioClear G50			
Ingredients Glutaraldehyde					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			10352(464)	old	
			10352(464)	old	
			10352(464)	old	
			10352(464)	old	
			10352(464)	old	
			10352(464)	old	
			10352(464)	old	
			10352(464)	old	
			10352(464)	old	
			AEATF II member (data being developed)	own	
			AEATF II member (data being developed)	own	
			AEATF II member (data being developed)	own	
			AEATF II member (data being developed)	own	
Signature 			Name and Title Stan Oslosky, Consultant to Weatherford		Date 7/7/14



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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Clearwater Int. LLC d/b/a Weatherford Eng. Chem. 2000 ST. JAMES PLACE, Houston, TX 77056	EPA Registration Number/File Symbol 59106-xx
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Active Ingredient(s) and/or representative test compound(s) Glutaraldehyde Ph. 713-836-4000	Date January 27, 2014
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General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Antimicrobial uses: Materials preservatives and Industrial processes and water systems.	Product Name BioClear G50
---	------------------------------

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
--	---

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature 	Date 1/17/2014	Typed or Printed Name and Title Stan Oslosky, Consultant to Weatherford
---------------	-------------------	--

Lantz, Tracy

From: Jiang, Chris
Sent: Wednesday, July 09, 2014 6:09 PM
To: Lantz, Tracy
Subject: 59106-1
Attachments: 59106-I_D419156_BioClearG50.doc



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY
AND POLLUTION
PREVENTION

July 9, 2014

DP BARCODE: D419156

MRID: 49375001, 49379501 49310101 49310102,
49310103, 49310104, 49310105

SUBJECT: Bio Clear G50

REG. NO. OR FILE SYMBOL: 59106-I

DOCUMENT TYPE: Product Chemistry Review

Manufacturing-use ☐ OR End-use Product ☒

INGREDIENTS (PC Codes): 043901

CAS Number: 111-30-8

TEST LAB: Product Safety Laboratories

SUBMITTER: Clearwater International, LLC

GUIDELINE: 830 Guidelines

COMMODITIES: Formulation

REVIEWER: Chris Jiang

ORGANIZATION: AD

APPROVER: Karen P. Hicks

APPROVED DATE:

COMMENT:



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY
AND POLLUTION
PREVENTION

July 9, 2014

MEMORANDUM

Subject: Review for 59106-I

From: Chris Jiang, Chemist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Thru: Karen P. Hicks, CT Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

To: Eric Miederhoff PM 33/Tracy Lantz
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Clearwater International, LLC

Formulation from Label

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
Glutaraldehyde	51.1
<u>Inert Ingredients</u>	49.9
Total	100

BACKGROUND:

The registrant has submitted a product chemistry package for this integrated manufacturing use product for non-food use. The package includes a cover letter, a label, Confidential Statements of Formula (CSFs) for the basic formulation and MRIDs 49375001, 49379501 49310101 49310102, 49310103, 49310104, and 49310105.

FINDINGS:

1. This product is identical in composition to 56106-O so all the comments will apply to this product.
2. The concentration of the active ingredient on the Confidential Statement of Formula (CSF dated 1/17/2014 for the basic formulation) may be consistent with the label declaration. The results of the preliminary analysis do not state whether the source is domestic or foreign. (See finding 7)
3. All ingredients are approved for non-food use.
4. The product identity and composition is **unacceptable** because of finding 1.
5. The description of the starting materials is **acceptable**.
6. The descriptions of the production process and formulation process are **acceptable**.
7. The preliminary analysis is **unacceptable** because report does not indicate whether the analysis was done on a foreign or domestic source of active ingredient.
8. The certified limits cannot be determined because of finding 6.
9. The enforcement analytical methods are **unacceptable**. The method does not tell the range at which the method is suitable.
10. The submittal of samples is **acceptable**.
11. The color, odor, and physical state are **acceptable** as the product is a colorless to slightly yellow liquid with a faint odor.
12. The density is **acceptable** as it was determined to be 9.4 lbs/gal.
13. The pH is **acceptable** as the pH of a 1% solution was determined to be 3.79.
14. The waiver request for stability to metal and metal ions is **acceptable**.

15. The oxidation/reduction waiver is **acceptable** as the product contains no oxidizing or reducing agents.
16. The flammability is **acceptable** as the product contains no combustible liquids..
17. The explodability is **acceptable** as the product is not potentially explosive.
18. A joint study for storage stability and corrosion characteristics is ongoing.
19. The viscosity is **acceptable** as the viscosity was determined to be 18.5 cSt at 20 °C and 5.9 cSt at 40 °C.
20. The miscibility is **acceptable** as the product is not to be diluted with organic solvents.
21. The dielectric breakdown voltage is **acceptable** as the product is not for use around electrical equipment.
22. The other physical/chemical properties are **acceptable**.

CONCLUSIONS:

Product Science Branch of Antimicrobials Division finds the CSF dated January 17, 2014 for the basic formulation and the data for 59106-O to be unacceptable for the reasons discussed in the findings. The registrant will need to remedy these issues for registration to proceed.

Lantz, Tracy

From: Miederhoff, Eric
Sent: Tuesday, July 08, 2014 9:53 AM
To: Hicks, Karen
Cc: Lantz, Tracy; Jiang, Chris
Subject: RE: Your reviews of 59106-I & O

Chris,

We understand you'll be able to do the chemistry reviews on these 2 products in the next day or so. Please advise us of your findings as quickly as possible.

Thank you,

Eric

From: Miederhoff, Eric
Sent: Tuesday, July 01, 2014 1:47 PM
To: Hicks, Karen
Cc: Lantz, Tracy
Subject: FW: Your reviews of 59106-I & O

Hi Karen,

This review was due 6/24.

We've spoken with Chris, and he is not able to get this done this week. We need to understand the status of these products' chemistry submissions in order to know what our pre-decisional notification should be.

Please advise us on when these reviews will be completed.

Thank you,

Eric Miederhoff
Acting Product Manager, Team 33
Regulatory Management Branch I
Antimicrobials Division
Office of Pesticide Programs
Environmental Protection Agency
703-347-8028

From: Lantz, Tracy
Sent: Monday, June 30, 2014 4:29 PM
To: Jiang, Chris

Cc: Hicks, Karen; Miederhoff, Eric
Subject: RE: Your review of 59106-I

Hi Chris,

Unless I missed your message, I have not heard from you on this review, 59106-I. Please provide an update as soon as possible.

I will be out of the office starting on July 15th, thus I cannot wait until the last minute to receive this review.

Thanks,

Tracy Lantz
Antimicrobials Division
Office of Pesticide Programs
Environmental Protection Agency
(703) 308-6415
Lantz.tracy@epa.gov

From: Lantz, Tracy
Sent: Wednesday, June 25, 2014 10:32 AM
To: Jiang, Chris
Cc: Hicks, Karen; Miederhoff, Eric
Subject: Your review of 59106-I

Hi Chris,

I know you are working on a chemistry review for me. It is DP420708 for 59106-I

It is due out of the agency on 7/24. Please provide an update.

I am hoping to have this review from you by Monday, 6/30 if possible.

Thanks,

Tracy Lantz
Antimicrobials Division
Office of Pesticide Programs
Environmental Protection Agency
(703) 308-6415
Lantz.tracy@epa.gov

DATA PACKAGE BEAN SHEET

Date: 03-Apr-2014

Page 1 of 2

Decision #: 487386

DP #: (419156)

PRIA

Parent DP #:

Submission #: 947069

E-Sub #:

*** Registration Information ***

Registration: 59106-I - BIO CLEAR G50

Company: 59106 - CLEARWATER INTERNATIONAL, LLC

Risk Manager: RM 33 - Marshall Swindell - (703) 308-6341 Room# PY1 S-8828

Risk Manager Reviewer: Tracy Lantz TLANTZ

Sent Date: _____

PRIA Due Date: 24-Jul-2014

Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (A532) UNREGISTERED SOURCE OF ACTIVE INGREDIENT;NEW PRODUCT;CITE-ALL DATA

Ingredients: 043901, Glutaraldehyde(51.1%)

*** Data Package Information ***

Expedite: ☒ Yes ☐ No

Date Sent: 03-Apr-2014

Due Back: _____

DP Ingredient: 043901, Glutaraldehyde

DP Title: Chemistry Data Review

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #: _____

Assigned To

Date In

Date Out

Organization: AD / PSB

Last Possible Science Due Date: 24-Jun-2014

Team Name: CTT

Science Due Date: _____

Reviewer Name: _____

Sub Data Package Due Date: _____

Contractor Name: _____

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

Can be printed on its own page

*** Data Package Instructions ***

I apologize for this package being late. I just received this information on 4/1/14.
Please indicate whether this data passes the technical screen by Wednesday, 4/9
Please review label, CSF and 4 studies, MRID 49310101-04

DP#: (419156)

*** Studies Sent for Review ***

Decision#: (487386)

MRID	MRID Status	Citation Reference	Guideline	86-5 Status
49310101		Oslosky, S. (2014) Product Chemistry Data: Part A: (Bio Clear 1000). Project Number: G50. Unpublished study prepared by Clearwater International, LLC. 24p.	830.1550/Product Identity and composition	Pass (12-Feb-2014)
49310101		Oslosky, S. (2014) Product Chemistry Data: Part A: (Bio Clear 1000). Project Number: G50. Unpublished study prepared by Clearwater International, LLC. 24p.	830.1600/Description of materials used to produce the product	Pass (12-Feb-2014)
49310101		Oslosky, S. (2014) Product Chemistry Data: Part A: (Bio Clear 1000). Project Number: G50. Unpublished study prepared by Clearwater International, LLC. 24p.	830.1620/Description of production process	Pass (12-Feb-2014)
49310101		Oslosky, S. (2014) Product Chemistry Data: Part A: (Bio Clear 1000). Project Number: G50. Unpublished study prepared by Clearwater International, LLC. 24p.	830.1670/Discussion of formation of impurities	Pass (12-Feb-2014)
49310101		Oslosky, S. (2014) Product Chemistry Data: Part A: (Bio Clear 1000). Project Number: G50. Unpublished study prepared by Clearwater International, LLC. 24p.	830.1700/Preliminary analysis	Pass (12-Feb-2014)
49310101		Oslosky, S. (2014) Product Chemistry Data: Part A: (Bio Clear 1000). Project Number: G50. Unpublished study prepared by Clearwater International, LLC. 24p.	830.1750/Certified limits	Pass (12-Feb-2014)
49310101		Oslosky, S. (2014) Product Chemistry Data: Part A: (Bio Clear 1000). Project Number: G50. Unpublished study prepared by Clearwater International, LLC. 24p.	830.1800/Enforcement analytical method	Pass (12-Feb-2014)
49310102		Valla, F. (2013) Glutaraldehyde Technical: Preliminary Analysis. Project Number: 34616, P809, 120418/5H. Unpublished study prepared by Eurofins/Product Safety Laboratories. 25p.	830.1700/Preliminary analysis	Pass (12-Feb-2014)
49310103		Wo, C. (2013) Glutaraldehyde Technical: Physical and Chemical Characteristics: Color, Physical State, Odor, Stability to Normal and Elevated Temperature, pH, UV/Visible Absorption, Boiling Point, Density/Relative Density, Dissociation Constant, Partition Coefficient and Water Solubility. Project Number: 34617, P804/TGAI, 120524/5H. Unpublished study prepared by Product Safety Laboratories. 38p.	830.6302/Color	Pass (12-Feb-2014)
49310103		Wo, C. (2013) Glutaraldehyde Technical: Physical and Chemical Characteristics: Color, Physical State, Odor, Stability to Normal and Elevated Temperature, pH, UV/Visible Absorption, Boiling Point, Density/Relative Density, Dissociation Constant, Partition Coefficient and Water Solubility. Project Number: 34617, P804/TGAI, 120524/5H. Unpublished study prepared by Product Safety Laboratories. 38p.	830.6303/Physical state	Pass (12-Feb-2014)
49310103		Wo, C. (2013) Glutaraldehyde Technical: Physical and Chemical Characteristics: Color, Physical State, Odor, Stability to Normal and Elevated Temperature, pH, UV/Visible Absorption, Boiling Point, Density/Relative Density, Dissociation Constant, Partition Coefficient and Water Solubility. Project Number: 34617, P804/TGAI, 120524/5H. Unpublished study prepared by Product Safety Laboratories. 38p.	830.6304/Odor	Pass (12-Feb-2014)
49310103		Wo, C. (2013) Glutaraldehyde Technical: Physical and Chemical Characteristics: Color, Physical State, Odor, Stability to Normal and Elevated Temperature, pH, UV/Visible Absorption, Boiling Point, Density/Relative Density, Dissociation Constant, Partition Coefficient and Water Solubility. Project Number: 34617, P804/TGAI, 120524/5H. Unpublished study prepared by Product Safety Laboratories. 38p.	830.6313/Stability to normal and elevated temperatures, metals, and metal ions	Pass (12-Feb-2014)

DP#: (419156)

*** Studies Sent for Review ***

Decision#: (487386)

MRID	MRID Status	Citation Reference	Guideline	86-5 Status
49310104		Cage, S. (2012) Glutaraldehyde Technical: Vapour Pressure. Project Number: MIB0029, 1107/2009. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 18p.	830.7950/Vapor pressure	Pass (12-Feb-2014)

Lantz, Tracy

From: Jiang, Chris
Sent: Thursday, May 08, 2014 1:37 PM
To: Lantz, Tracy
Cc: Noble, Velma
Subject: 59106-O and 59106-I both pass the tech screen

They appear to be using the same data. One is a EUP and the other is a MUP.

chemistry

Lantz, Tracy

From: Lantz, Tracy
Sent: Thursday, April 10, 2014 6:30 PM
To: 'stanley.oslosky@weatherford.com'
Cc: Swindell, Marshall
Subject: FW: 59106-I-10 day letter
Attachments: [Untitled].pdf

Tracking:	Recipient	Delivery
	'stanley.oslosky@weatherford.com'	
	Swindell, Marshall	Delivered: 4/10/2014 6:30 PM

Please confirm that you have received this correspondence.

Please see the attached letter signed by Marshall Swindell.
The text of this letter is repeated below.

OPP Decision Number: 487386
EPA Reg. Number: 59106-I
Product Name: BioClear G50
EPA Receipt Date: February 3, 2014
EPA Company Number: 59106
Company Name: Clearwater International LLC d/b/a Weatherford Engineered Chemistry

Stan Oslosky
Consultant to Weatherford
2000 St. James Place, 7th Floor
Houston, TX 77056

Dear Mr. Oslosky:

The Agency has completed its preliminary technical screening of your application pursuant to Section 33(f)(4)(B)(i)(II) of the Federal Insecticide, Fungicide, and Rodenticide (FIFRA) Act, as amended by the Pesticide Registration Improvement Extension Act. The Agency has determined that your application has not passed the preliminary technical screen and therefore is subject to rejection if the application is not corrected.

The submission has failed the Technical Screen for the following reasons:

You have indicated that this product is a me-too of 464-691. Based on the formulation submitted for this product, BioClear G50 is NOT a me-too of 464-691.

The following chemistry guidelines have not been addressed. These guideline must be addressed in order for EPA to continue the review of this application: 830.1900, 830.6314, 830.6315, 830.6316, 830.6317, 830.6319, 830.6320, and 830.7100. You may indicate that the data associated with 830.6317 and 830.6320 will be submitted for review at a later date.

In order for the review of your product to continue, you will need to correct your application by addressing the item(s) listed above within 10 business days of the date you received this letter. Corrections must be received by EPA by the 10th business day. EPA recommends sending your complete set of corrections by email to the contact listed below to ensure they are timely received. If studies or confidential information are being submitted by mail, a complete courtesy

copy received by email by the deadline will be considered timely. If you cannot correct the application [or do not respond] within 10 business days, your application will be rejected.

At this time you could also choose to withdraw your application. If you have questions, please contact Marshall Swindell at Swindell.marshall@epa.gov or (703) 308-6341 or Tracy Lantz at Lantz.tracy@epa.gov or (703) 308-6415.

Tracy Lantz
Antimicrobials Division
Office of Pesticide Programs
Environmental Protection Agency
(703) 308-6415
Lantz.tracy@epa.gov

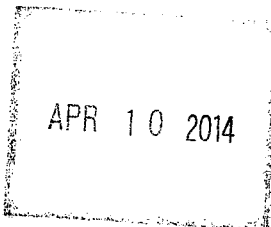
-----Original Message-----

From: EZTech_Printer [mailto:EZTek@epa.gov]
Sent: Thursday, April 10, 2014 6:22 PM
To: Lantz, Tracy
Subject: 59106-I 10 day letter

Please open the attached document. This document was digitally sent to you using an HP Digital Sending device.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: 487386
EPA Reg. Number: 59106-I
Product Name: BioClear G50
EPA Receipt Date: February 3, 2014
EPA Company Number: 59106
Company Name: Clearwater International LLC d/b/a Weatherford Engineered Chemistry

Stan Oslosky
Consultant to Weatherford
2000 St. James Place, 7th Floor
Houston, TX 77056

Dear Mr. Oslosky:

The Agency has completed its preliminary technical screening of your application pursuant to Section 33(f)(4)(B)(i)(II) of the Federal Insecticide, Fungicide, and Rodenticide (FIFRA) Act, as amended by the Pesticide Registration Improvement Extension Act. The Agency has determined that your application has not passed the preliminary technical screen and therefore is subject to rejection if the application is not corrected.

The submission has failed the Technical Screen for the following reasons:

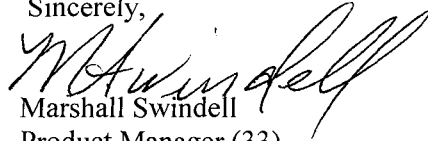
You have indicated that this product is a me-too of 464-691. Based on the formulation submitted for this product, BioClear G50 is NOT a me-too of 464-691.

The following chemistry guidelines have not been addressed. These guideline must be addressed in order for EPA to continue the review of this application: 830.1900, 830.6314, 830.6315, 830.6316, 830.6317, 830.6319, 830.6320, and 830.7100. You may indicate that the data associated with 830.6317 and 830.6320 will be submitted for review at a later date.

In order for the review of your product to continue, you will need to correct your application by addressing the item(s) listed above within 10 business days of the date you received this letter. Corrections must be received by EPA by the 10th business day. EPA recommends sending your complete set of corrections by email to the contact listed below to ensure they are timely received. If studies or confidential information are being submitted by mail, a complete courtesy copy received by email by the deadline will be considered timely. If you cannot correct the application [or do not respond] within 10 business days, your application will be rejected.

At this time you could also choose to withdraw your application. If you have questions, please contact Marshall Swindell at Swindell.marshall@epa.gov or (703) 308-6341 or Tracy Lantz at Lantz.tracy@epa.gov or (703) 308-6415.

Sincerely,

A handwritten signature in black ink, appearing to read "M. Swindell", written over the printed name.

Marshall Swindell
Product Manager (33)
Regulatory Management Branch I
Antimicrobials Division (7510P)

NOTE TO THE FILE

April 3, 2014

Subject: Determination of Similarity For EPA Reg#s 59106-I and 59106-O

In reference to two pending applications 59106-I and 59106-O I met with Mark Perry (AD/PSB). Both applications referenced two currently registered products (EPA Reg# 464-694 and 464-691) as being substantially similar to their proposed formulations. The formulations for EPA File Symbols 59106-I and 59106-O are identical in composition. Although the registered 464-694 and 464-691 products contain one additional component it is at a very low level. And as it is not present in the pending formulations any changes in Toxicity if any would be less for the pending applications. Mark agreed with this rationale and thus the applications are determined to be substantially similar to the referenced products above.

Marshall Swindell, PM 33

Antimicrobials Division

4/3/14

59106-I

Marshall,

Here are the BEANs for the similarity clinic. I gave you the “data” (CSFs and labels for this product and the me-too product) on Monday night. Since our 45 day screen deadline is 4/10 you said you would speak to Ian and ask for a quick turn around.

Please let me know if you have spoken to Ian about this similarity clinic.

Thanks,

Tracy

DATA PACKAGE BEAN SHEET

Date: 03-Apr-2014

Page 1 of 1

Decision #: 487386

DP #: (419126)

PRIA

Parent DP #:

Submission #: 947069

E-Sub #:

*** Registration Information ***

Registration: 59106-I - BIO CLEAR G50

Company: 59106 - CLEARWATER INTERNATIONAL, LLC

Risk Manager: RM 33 - Marshall Swindell - (703) 308-6341 Room# PY1 S-8828

Risk Manager Reviewer: Tracy Lantz TLANTZ

Sent Date: _____

PRIA Due Date: 24-Jul-2014

Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (A532) UNREGISTERED SOURCE OF ACTIVE INGREDIENT;NEW PRODUCT;CITE-ALL DAT

Ingredients: 043901, Glutaraldehyde(51.1%)

*** Data Package Information ***

Expedite: ☒ Yes ☐ No

Date Sent: 03-Apr-2014

Due Back: _____

DP Ingredient: 043901, Glutaraldehyde

DP Title: Similarity Clinic

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #: _____

Assigned To

Date In

Date Out

Organization: AD / PSB

Last Possible Science Due Date: ~~24-Jul-2014~~

Team Name: CTT

Science Due Date: 09-Apr-2014

Reviewer Name: _____

Sub Data Package Due Date: _____

Contractor Name: _____

*** Studies Sent for Review ***

No Studies

*** Additional Data Package for this Decision ***

No Additional Data Packages

*** Data Package Instructions ***

I apologize for the fact that this package is late. I rec'd it 4/1/14. Please reply as to whether this product passes the similarity clinic by Wednesday, 4/9. I have provided the CSF and label of the cited product, 464-691.

DATA PACKAGE BEAN SHEET

Date: 03-Apr-2014

Page 1 of 1

Decision #: 487386

DP #: (419126)

PRIA

Parent DP #:

Submission #: 947069

E-Sub #:

*** Registration Information ***

Registration: **59106-I - BIO CLEAR G50**

Company: 59106 - CLEARWATER INTERNATIONAL, LLC

Risk Manager: RM 33 - Marshall Swindell - (703) 308-6341 Room# PY1 S-8828

Risk Manager Reviewer: Tracy Lantz TLANTZ

Sent Date: _____

PRIA Due Date: 24-Jul-2014

Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (A532) UNREGISTERED SOURCE OF ACTIVE INGREDIENT;NEW PRODUCT;CITE-ALL DATA

Ingredients: 043901, Glutaraldehyde(51.1%)

*** Data Package Information ***

Expedite: ☒ Yes ☐ No

Date Sent: 03-Apr-2014

Due Back: _____

DP Ingredient: 043901, Glutaraldehyde

DP Title: Similarity Clinic

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #: _____

Assigned To

Date In

Date Out

Organization: AD / PSB

Last Possible Science Due Date: ~~24-Jul-2014~~

Team Name: CTT

Science Due Date: 09-Apr-2014

Reviewer Name: _____

Sub Data Package Due Date: _____

Contractor Name: _____

*** Studies Sent for Review ***

No Studies

*** Additional Data Package for this Decision ***

No Additional Data Packages

*** Data Package Instructions ***

I apologize for the fact that this package is late. I rec'd it 4/1/14. Please reply as to whether this product passes the similarity clinic by Wednesday, 4/9. I have provided the CSF and label of the cited product, 464-691.

4/3/14

59106-I

Marshall,

Here are the BEANs for the similarity clinic. I gave you the "data" (CSFs and labels for this product and the me-too product) on Monday night. Since our 45 day screen deadline is 4/10 you said you would speak to Ian and ask for a quick turn around.

Please let me know if you have spoken to Ian about this similarity clinic.

Thanks,

Tracy

4/3/14
Marshall spoke to
Mark P. - who
said OK - may cite product
Marshall will
write a note

DATA PACKAGE BEAN SHEET

Date: 03-Apr-2014

Page 1 of 1

Decision #: 487386

DP #: (419126)

PRIA

Parent DP #:

Submission #: 947069

E-Sub #:

*** Registration Information ***

Registration: **59106-I - BIO CLEAR G50**

Company: 59106 - CLEARWATER INTERNATIONAL, LLC

Risk Manager: RM 33 - Marshall Swindell - (703) 308-6341 Room# PY1 S-8828

Risk Manager Reviewer: Tracy Lantz TLANTZ

Sent Date:

PRIA Due Date: 24-Jul-2014

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (A532) UNREGISTERED SOURCE OF ACTIVE INGREDIENT; NEW PRODUCT; CITE-ALL DATA

Ingredients: 043901, Glutaraldehyde(51.1%)

*Tracy's
copy*

*** Data Package Information ***

Expedite: ☒ Yes ☐ No

Date Sent: 03-Apr-2014

Due Back:

DP Ingredient: 043901, Glutaraldehyde

DP Title: Similarity Clinic

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: AD / PSB

Last Possible Science Due Date: 24-Jun-2014

Team Name: CTT

Science Due Date: 09-Apr-2014

Reviewer Name:

Sub Data Package Due Date:

Contractor Name:

*** Studies Sent for Review ***

No Studies

*** Additional Data Package for this Decision ***

No Additional Data Packages

*** Data Package Instructions ***

I apologize for the fact that this package is late. I rec'd it 4/1/14. Please reply as to whether this product passes the similarity clinic by Wednesday, 4/9. I have provided the CSF and label of the cited product, 464-691.

*gave labels +
CSFs
to Marshall
on 4/1/14
Marshall
said
he would
ask Ian
for a one
day
review.*

DATA PACKAGE BEAN SHEET

Date: 03-Apr-2014

Page 1 of 1

Decision #: 487386

DP #: (419126)

PRIA

Parent DP #:

Submission #: 947069

E-Sub #:

*** Registration Information ***

Registration: **59106-I - BIO CLEAR G50**

Company: 59106 - CLEARWATER INTERNATIONAL, LLC

Risk Manager: RM 33 - Marshall Swindell - (703) 308-6341 Room# PY1 S-8828

Risk Manager Reviewer: Tracy Lantz TLANTZ

Sent Date: _____

PRIA Due Date: 24-Jul-2014

Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (A532) UNREGISTERED SOURCE OF ACTIVE INGREDIENT;NEW PRODUCT;CITE-ALL DA1

Ingredients: 043901, Glutaraldehyde(51.1%)

*** Data Package Information ***

Expedite: ☒ Yes ☐ No

Date Sent: 03-Apr-2014

Due Back: _____

DP Ingredient: 043901, Glutaraldehyde

DP Title: Similarity Clinic

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #: _____

Assigned To

Date In

Date Out

Organization: AD / PSB

Last Possible Science Due Date: 24-Jun-2014

Team Name: CTT

Science Due Date: 09-Apr-2014

Reviewer Name: _____

Sub Data Package Due Date: _____

Contractor Name: _____

*** Studies Sent for Review ***

No Studies

*** Additional Data Package for this Decision ***

No Additional Data Packages

*** Data Package Instructions ***

I apologize for the fact that this package is late. I rec'd it 4/1/14. Please reply as to whether this product passes the similarity clinic by Wednesday, 4/9. I have provided the CSF and label of the cited product, 464-691.

21-Day Screen Completed by
Contractor

21-Day Expires on 2/24/14

Jacket # 59106-F

MRID# 493101

Content Screen: Recommend to Pass/Fail

11-3 Review: Pass/Fail/NA

Overall Status: Recommend to Pass/Fail

Transfer This Jacket to:

Marshall Swindell

myd

Memorandum

Date: 2/10/14

To: PM 33, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a:

- ☒ fully accepted submission
- ☐ partially accepted submission
- ☐ rejected submission

Tracy
rec'd
4/1/14



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

February 07, 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

CLEARWATER INTERNATIONAL, LLC
2000 ST. JAMES PLACE, 7TH FLOOR
HOUSTON, TX 77056

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 03-FEB-14. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Receipt for Section 3

S: 947069

Milestone Email:

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Print Letter

Application Type: New Registration

Fee For Service: ☒ Yes ☐ No

Enter More Information

Billable: ☒ Yes ☐ No

Tracking

Company: 59106 CLEARWATER INTERNATIONAL, LLC



Risk Manager: Antimicrobials Division, Risk Management Team 33

Product #: 59106-1 Product Name: BIO CLEAR G50

Override#:

Me Too Section 3: 464-691

Me Too

Product Name: UCARGIDE 250 ANTIMICROBIAL

Application Date: 27-Jan-2014

OPP Rec'd Date: 03-Feb-2014

Front End Date: 03-Feb-2014

Risk Manager Send Date:

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

View/Edit

Receipt Description:

New product registration application

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:



Weatherford®

49310100

Office of Pesticide Programs (7504P) REGFEE
U. S. Environmental Protection Agency
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

January 29, 2014

ATTENTION: Marshall Swindell
Product Manager, Team 33

SUBJECT: Clearwater International, LLC d/b/a Weatherford Engineered Chemistry (59106)
BioClear G50 Antimicrobial and BioClear 2500 Antimicrobial
Registration applications

Dear Marshall;

On behalf of Clearwater International, LLC, I am submitting applications for the registration of the above two products. Both are an approximate 50% solution of Glutaraldehyde and are chemically identical. Clearwater is applying for BioClear G50 as a Manufacturing Use Product and BioClear 2500 as an End Use Product. All required document are enclosed and formatted.

1. BioClear G50 Antimicrobial –MUP
2. BioClear 2500 Antimicrobial –EUP

Thank you for your assistance with this application and if you or your staff have any questions, please call me at 724-316-0689 or e-mail me at Stanley.oslosky@weatherford.com.

Sincerely,

Stan Oslosky
Consultant to Weatherford
Stanley.Oslosky@weatherford.com

Engineered Chemistry

Weatherford
2000 St. James Place
Houston, Texas 77056
USA

+1.713.968.4000
+1.713.969.2401 Fax

www.weatherford.com

TRANSMITTAL DOCUMENT

Transmittal Date: January 30, 2014
Name and Address of Submitter: CLEARWATER INTERNATIONAL LLC, D/B/A WEATHERFORD
ENGINEERED CHEMISTRY
HOUSTON, TX 77056
**Regulatory action in support of which
this package is submitted:** *Information to support the registration of BioClear G50 (MUP)*
EPA Reg. No./File Symbol: 59106-XX
Alternate test material name Glutaraldehyde

Administrative Materials

	Transmittal Document
	Cover Letter
	Pay.gov acknowledgement e-mail
	List of AEATF II member companies
EPA Form 8570-1	Application for Pesticide
	Label (5 copies)
EPA Form 8570-4	Confidential statement of formula (3 copies)
EPA Form 8570-34	Certification with Respect to Citation of Data
EPA Form 8570-35	Data Matrix—Listing Offer-to-pay recipients
EPA Form 8570-35	Data Matrix
EPA Form 8570-35	Data Matrix (masked)

Volume No.	Citation	MRID Number
1	Oslosky, 2014, Product Chemistry Data. Unpublished study by Clearwater International d/b/a Weatherford, 7 pages. With Confidential Attachment 17 pages. (3 copies).	49310101
2	Valla, Sept. 27, 2013; Glutaraldehyde Technical: Preliminary Analysis. Unpublished study by Eurofins Product Safety Laboratories 20 pages. Confidential Attachment 5 pages (3 copies).	49310102
3	Wo, Sept. 27, 2013; Glutaraldehyde Technical: Physical and Chemical Characteristics: Color, Physical State, Odor, Stability to Normal and Elevated Temperatures, pH, UV/Visible Absorption, Boiling Point, Density/Relative Density, Dissociation Constant, Partition Coefficient and Water Solubility. Unpublished study by Eurofins, Product Safety Laboratories 38 pages. (3 copies).	49310103
4	Cage, Oct. 16, 2012; Glutaraldehyde Technical: Vapor Pressure. Unpublished study by Huntington Life Sciences Ltd., 18 pages. (3 copies).	49310104
7	Oslosky, 2014, Waiver Request for Product Chemistry Data. Unpublished study by Clearwater International d/b/a Weatherford, 6 pages.	49310105

Product: BioClear G50
Submitter Stan Oslosky
Company: CLEARWATER INTERNATIONAL LLC, D/B/A WEATHERFORD ENGINEERED
CHEMISTRY
Phone: 724-316-0689
E-mail: Stsnley.Oslosky@Weatherford.com

***Note to reviewer—A concurrent EUP that is chemically identical is also being submitted for which the above studies are also relevant**



Office of Pesticide Programs (7504P) REGFEE
U. S. Environmental Protection Agency
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

January 29, 2014

ATTENTION: Marshall Swindell
Product Manager, Team 33

SUBJECT: Clearwater International, LLC d/b/a Weatherford Engineered Chemistry (59106)
BioClear G50 Antimicrobial and BioClear 2500 Antimicrobial
Registration applications

Dear Marshall;

On behalf of Clearwater International, LLC, I am submitting applications for the registration of the above two products. Both are an approximate 50% solution of Glutaraldehyde and are chemically identical. Clearwater is applying for BioClear G50 as a Manufacturing Use Product and BioClear 2500 as an End Use Product. All required document are enclosed and formatted.

1. BioClear G50 Antimicrobial –MUP
2. BioClear 2500 Antimicrobial –EUP

Thank you for your assistance with this application and if you or your staff have any questions, please call me at 724-316-0689 or e-mail me at Stanley.oslosky@weatherford.com.

Sincerely,

Stan Oslosky
Consultant to Weatherford
Stanley.Oslosky@weatherford.com

Engineered Chemistry

Weatherford
2000 St. James Place
Houston, Texas 77056
USA

+1.713.968.4000
+1.713.969.2401 Fax

www.weatherford.com

TRANSMITTAL DOCUMENT

Transmittal Date: January 30, 2014
 Name and Address of Submitter: CLEARWATER INTERNATIONAL LLC, D/B/A WEATHERFORD
 ENGINEERED CHEMISTRY
 HOUSTON, TX 77056
 Regulatory action in support of which
 this package is submitted: *Information to support the registration of BioClear G50 (MUP)*
 EPA Reg. No./File Symbol: 59106-XX
 Alternate test material name: Glutaraldehyde

Administrative Materials

	Transmittal Document
	Cover Letter
	Pay.gov acknowledgement e-mail
	List of AEATF II member companies
EPA Form 8570-1	Application for Pesticide Label (5 copies)
EPA Form 8570-4	Confidential statement of formula (3 copies)
EPA Form 8570-34	Certification with Respect to Citation of Data
EPA Form 8570-35	Data Matrix—Listing Offer-to-pay recipients
EPA Form 8570-35	Data Matrix
EPA Form 8570-35	Data Matrix (masked)

Volume No.	Citation	MRID Number
1	Oslosky, 2014, Product Chemistry Data. Unpublished study by Clearwater International d/b/a Weatherford, 7 pages. With Confidential Attachment 17 pages. (3 copies).	
2	Valla, Sept. 27, 2013; Glutaraldehyde Technical: Preliminary Analysis. Unpublished study by Eurofins Product Safety Laboratories 20 pages. Confidential Attachment 5 pages (3 copies).	
3	Wo, Sept. 27, 2013; Glutaraldehyde Technical: Physical and Chemical Characteristics: Color, Physical State, Odor, Stability to Normal and Elevated Temperatures, pH, UV/Visible Absorption, Boiling Point, Density/Relative Density, Dissociation Constant, Partition Coefficient and Water Solubility. Unpublished study by Eurofins, Product Safety Laboratories 38 pages. (3 copies).	
4	Cage, Oct. 16, 2012; Glutaraldehyde Technical: Vapor Pressure. Unpublished study by Huntington Life Sciences Ltd., 18 pages. (3 copies).	
7	Oslosky, 2014, Waiver Request for Product Chemistry Data. Unpublished study by Clearwater International d/b/a Weatherford, 6 pages.	

Product: BioClear G50
 Submitter: Stan Oslosky
 Company: CLEARWATER INTERNATIONAL LLC, D/B/A WEATHERFORD ENGINEERED
 CHEMISTRY
 Phone: 724-316-0689
 E-mail: Stsnley.Oslosky@Weatherford.com

***Note to reviewer—A concurrent EUP that is chemically identical is also being submitted for which the above studies are also relevant**



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

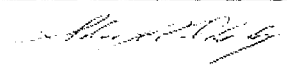
Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registrations and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

DATA MATRIX

Date January 27, 2014	EPA Reg. No./File Symbol 59106-xx	Page 1 of 2
Applicant's/Registrant's Name & Address CLEARWATER INTERNATIONAL LLC, D/B/A WEATHERFORD ENGINEERED CHEMISTRY, HOUSTON, TX 77056		Product: BioClear G50

Ingredients Glutaraldehyde; LIST OF DATA SUBMITTER TO WHOM OFFER-TO-PAY LETTERS WERE SUBMITTED

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Product Chemistry		59106	OWN	Vol. 1
830.1550	Product identity and composition		59106	OWN	Vol. 1
830.1600	Description of starting materials		59106	OWN	Vol. 1
830.1620	Description of production process		59106	OWN	Vol. 1
830.1670	Discussion of formation of impurities		59106	OWN	Vol. 1
830.1700	Preliminary Analysis of Product		59106	OWN	Vol. 1
830.1750	Certification of limits		59106	OWN	Vol. 2
830.1800	Enforcement Analytical methods		59106	OWN	Vol. 1
830.1900	Submittal of Samples		59106	OWN	Vol. 1
830.6302	Color		59106	OWN	Vol. 3
830.6303	Physical State		59106	OWN	Vol. 3
830.6304	Odor		59106	OWN	Vol. 3
830.6313	Stability –Temperature Stability		59106	OWN	Vol. 3
830.6313	Stability –Metal Ions		59106	OWN	Waiver Vol. 5
830.6314	Oxidizing/reducing reaction		59106	OWN	Waiver Vol. 5
830.6315	Flammability		59106	OWN	Waiver Vol. 5
830.6316	Explodability		59106	OWN	Waiver Vol. 5

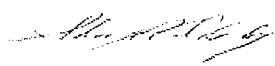
Signature 	Name and Title Stan Oslosky, Consultant to Weatherford	Date 1/27/14
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registrations and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

DATA MATRIX

Date January 27, 2014		EPA Reg. No./File Symbol 59106-xx		Page 2 of 2	
Applicant's/Registrant's Name & Address CLEARWATER INTERNATIONAL LLC, D/B/A WEATHERFORD ENGINEERED CHEMISTRY, HOUSTON, TX 77056		Product: BioClear G50			
Ingredients 1,2-Benzisothiazoline-3-one (BIT)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6317	Storage stability		59106 (provide when done)	OWN	Waiver Vol. 5
830.6319	Miscibility		59106	OWN	Waiver Vol. 5
830.6320	Corrosion Characteristics		59106 (provide when done)	OWN	Waiver Vol. 5
830.6321	Dielectric breakdown voltage		59106	OWN	Waiver Vol. 5
830.7000	pH		59106	OWN	Vol. 3
830.7220	Boiling Point		59106	OWN	Vol. 3
830.7300	Density		59106	OWN	Vol. 3
830.7370	Dissociation Constant		59106	OWN	Waiver Vol. 5
830.7550	Octanol/Water Partition Coefficient		59106	OWN	Vol. 3
830.7840	Solubility – Water		59106	OWN	Vol. 3
830.7950	Vapor Pressure		59106	OWN	Vol. 4
870.xxxx	Toxicology		(using the cite-all method of support)		
850.xxxx	Antimicrobial Nontarget Organism		(using the cite-all method of support)		
850.xxxx	Nontarget Plant Protection		(using the cite-all method of support)		
875.xxxx	Antimicrobial Applicator Exposure		(using the cite-all method of support)		AEATF II member
875.xxxx	Antimicrobial Post-Application Exp.		(using the cite-all method of support)		AEATF II member
Signature 			Name and Title Stan Oslosky, Consultant to Weatherford		Date 1/27/14

United States Environmental Protection Agency Washington, DC 20460		<input checked="" type="checkbox"/> Registration <input type="checkbox"/> Amendment <input type="checkbox"/> Other	OPP Identifier Number
Application for Pesticide - Section I			
1. Company / Product Number <u>59106-xx</u>		2. EPA Product Manager <u>Swindell</u>	
4. Company / Product (Name) <u>BioClear G50</u>		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
5. Name and Address of Applicant (include ZIP Code) <u>CLEARWATER INTERNATIONAL, LLC</u> <u>D/B/A WEATHERFORD ENGINEERED CHEMISTRY</u> <u>2000 ST. JAMES PLACE, 7th Floor</u> <u>HOUSTON, TX 770956</u> <input type="checkbox"/> Check of this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. <u>464-691</u> Product Name <u>Ucarcide 250</u>	
Section - II			
<input type="checkbox"/> Amendment - Explain Below. <input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input checked="" type="checkbox"/> "Me Too" Application <input type="checkbox"/> Notification - Explain below. <input type="checkbox"/> Other - Explain below.			
Explanation: Use additional page(s) if necessary. (For section I and Section II.) This is an EPA Number A532. This is an MUP with a new source of a previously registered active. This new product is chemically identical to the above referenced products. A five batch analysis is provided.			
Section - III			
1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt. _____ No. per container _____	Water Soluble Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Package Wgt _____ No. per container _____	2. Type of Container <input checked="" type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify) <u>Baked Phenolic-line steel</u>
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) retail Container <u>25 kg box</u>	5. Location of Label Directions <u>Container</u>
6. Manner in Which Label is affixed to Product		<input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glues <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____	
Section - IV			
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary. To process this application.)			
Name <u>Stan Oslosky</u>		Title <u>Consultant to Weatherford</u>	Telephone No. (Include Area Code) <u>724-316-0689</u>
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 		3. Title <u>Consultant to Weatherford</u>	
4. Typed Name <u>Stan Oslosky</u>		5. Date <u>27-Jan-14</u>	

DATA PACKAGE BEAN SHEET

Date: 09-Apr-2014

Page 1 of 2

Decision #: 487386

DP #: (419156)

PRIA

Parent DP #:

Submission #: 947069

E-Sub #:

*** Registration Information ***

Registration: 59106-I - BIO CLEAR G50

Company: 59106 - CLEARWATER INTERNATIONAL, LLC

Risk Manager: RM 33 - Marshall Swindell - (703) 308-6341 Room# PY1 S-8828

Risk Manager Reviewer: Tracy Lantz TLANTZ

Sent Date: PRIA Due Date: 24-Jul-2014

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (A532) UNREGISTERED SOURCE OF ACTIVE INGREDIENT;NEW PRODUCT;CITE-ALL DAT

Ingredients: 043901, Glutaraldehyde(51.1%)

*** Data Package Information ***

Expedite: ☒ Yes ☐ No

Date Sent: 03-Apr-2014

Due Back:

DP Ingredient: 043901, Glutaraldehyde

DP Title: Chemistry Data Review

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: AD / PSB

03-Apr-2014

Last Possible Science Due Date: 24-Jun-2014

Team Name: CTT

03-Apr-2014

Science Due Date:

Reviewer Name: Jiang, Chris

04-Apr-2014

Sub Data Package Due Date:

Contractor Name:

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

Can be printed on its own page

*** Data Package Instructions ***

I apologize for this package being late. I just recieved this inforamtion on 4/1/14.
Please indicate whether this data passes the technical screen by Wednesday, 4/9
Please review label, CSF and 4 studies, MRID 49310101-04

DATA PACKAGE BEAN SHEET

Date: 05-Jun-2014

Page 1 of 2

Decision #: 487386

DP #: (420708)

PRIA

Parent DP #:

Submission #: 952214

E-Sub #:

*** Registration Information ***

Registration: 59106-I - BIO CLEAR G50

Company: 59106 - CLEARWATER INTERNATIONAL, LLC

Risk Manager:

Risk Manager Reviewer: Tracy Lantz TLANTZ

Sent Date: 13-May-2014

PRIA Due Date: 24-Jul-2014

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (A532) UNREGISTERED SOURCE OF ACTIVE INGREDIENT;NEW PRODUCT;CITE-ALL DAT

Ingredients: 043901, Glutaraldehyde(51.1%)

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 05-Jun-2014

Due Back:

DP Ingredient: 043901, Glutaraldehyde

DP Title: Additional chemistry data in reply to screen

CSF Included: ☐ Yes ☒ No

Label Included: ☐ Yes ☒ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: AD / PSB

Last Possible Science Due Date: 24-Jun-2014

Team Name: CTT

Science Due Date:

Reviewer Name:

Chris

6/5

Sub Data Package Due Date:

Contractor Name:

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

Can be printed on its own page

*** Data Package Instructions ***

Please review the additional chemistry study, MRID 49375201 in response to the chemistry screen deficiencies



Weatherford

49375200

Tracy Lantz
Antimicrobials Division
Office of Pesticide Programs
U. S. Environmental Protection Agency
One Potomac Yard, XX Floor, Room XXXX
2777 South Crystal Drive
Arlington, VA 22202

ATTENTION: Tracy Lantz (703) 308-6415
Product Management, Team 33

SUBJECT: Clearwater International, LLC d/b/a Weatherford Engineered Chemistry (59106)
BioClear G50
File symbol 59106-I

Dear Tracy;

In response to your e-mail dated 4-10-2014, please accept this response as outlined specifically below.
Your e-mail stated:

"The submission has failed the Technical Screen for the following reasons: You have indicated that this product is a me-too of 464-691. Based on the formulation submitted for this product, BioClear G50 is NOT a me-too of 464-691.

The following chemistry guidelines have not been addressed. These guidelines must be addressed in order for EPA to continue the review of this application: 830.1900, 830.6314, 830.6315, 830.6316, 830.6317, 830.6319, 830.6320, and 830.7100. You may indicate that the data associated with 830.6317 and 830.6320 will be submitted for review at a later date."

In the enclosed document entitled, *"Detailed Glutaraldehyde Chemistry"* I explain the pre-reaction chemistry of glutaraldehyde and its final composition to show equivalency to Registration number 464-491.

In the document also enclosed titled *"Waiver Request for Product Chemistry Data, BioClear G50, EPA registration number 59106-O"*, I have addressed the following: 830.1900, 830.6314, 830.6315, 830.6316, 830.6317, 830.6319, and 830.6320. For 830.7100 I have commissioned a viscosity determination, at an increased cost for an accelerated result. I expect to have a formal study completed by April 25, 2014. I will e-mail the viscosity study as soon as it is available. For test guideline numbers 830.6317 and 830.6320, concurrent studies are already in progress and an initial, preliminary result is included as an addendum to the above referenced Waiver request document.

Thank you for your assistance with this application and if you or your staff have any questions, please call me at 724-316-0689 or e-mail me at Stanley.oslosky@weatherford.com.

Sincerely,

Stan Oslosky
Consultant to Weatherford
Stanley.Oslosky@weatherford.com
Engineered Chemistry

Weatherford
2000 St. James Place
Houston, Texas 77056
USA

+1.713.968.4000
+1.713.969.2401 Fax

www.weatherford.com

TRANSMITTAL DOCUMENT

Transmittal Date: April 23, 2014
Name and Address of Submitter: CLEARWATER INTERNATIONAL LLC, D/B/A
WEATHERFORD ENGINEERED CHEMISTRY
HOUSTON, TX 77056
Regulatory action in support of which this package is submitted: *Information to support the registration of BioClear G50 (MUP)*
EPA Reg. No./File Symbol: 59106-I
Alternate test material name Glutaraldehyde

Administrative Materials

Transmittal Document
Cover Letter

Volume No.	Citation	MRID Number
1	Oslosky, 2014, Detailed Product Chemistry Data. Unpublished study by Clearwater International d/b/a Weatherford, 9 pages. With Confidential Attachment. (1 e-mail copy, 3 hard copies).	49375201
2	Oslosky, 2014, Waiver Request for Product Chemistry Data. Unpublished study by Clearwater International d/b/a Weatherford, 7 pages. (1 e-mailed copy and 3 hard copies)	49375202

Product: BioClear G50
Submitter Stan Oslosky
Company: CLEARWATER INTERNATIONAL LLC, D/B/A WEATHERFORD
ENGINEERED CHEMISTRY
Phone: 724-316-0689
E-mail: Stsnley.Oslosky@Weatherford.com

DATA PACKAGE BEAN SHEET

Date: 03-Apr-2014

Page 1 of 2

Decision #: 487386

DP #: (419156)

PRIA

Parent DP #:

Submission #: 947069

E-Sub #:

*** Registration Information ***

Registration: **59106-I - BIO CLEAR G50**

Company: 59106 - CLEARWATER INTERNATIONAL, LLC

Risk Manager: RM 33 - Marshall Swindell - (703) 308-6341 Room# PY1 S-8828

Risk Manager Reviewer: Tracy Lantz TLANTZ

Sent Date: _____

PRIA Due Date: 24-Jul-2014

Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (A532) UNREGISTERED SOURCE OF ACTIVE INGREDIENT;NEW PRODUCT;CITE-ALL DATA

Ingredients: 043901, Glutaraldehyde(51.1%)

*** Data Package Information ***

Expedite: ☒ Yes ☐ No

Date Sent: 03-Apr-2014

Due Back: _____

DP Ingredient: 043901, Glutaraldehyde

DP Title: Chemistry Data Review

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #: _____

Assigned To

Date In

Date Out

Organization: AD / PSB

Last Possible Science Due Date: 24-Jun-2014

Team Name: CTT

Science Due Date: _____

Reviewer Name: _____

Sub Data Package Due Date: _____

Contractor Name: _____

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

Can be printed on its own page

*** Data Package Instructions ***

I apologize for this package being late. I just received this information on 4/1/14.
Please indicate whether this data passes the technical screen by Wednesday, 4/9
Please review label, CSF and 4 studies, MRID 49310101-04

MRID	MRID Status	Citation Reference	Guideline	86-5 Status
49310103		Wo, C. (2013) Glutaraldehyde Technical: Physical and Chemical Characteristics: Color, Physical State, Odor, Stability to Normal and Elevated Temperature, pH, UV/Visible Absorption, Boiling Point, Density/Relative Density, Dissociation Constant, Partition Coefficient and Water Solubility. Project Number: 34617, P804/TGAI, 120524/5H. Unpublished study prepared by Product Safety Laboratories. 38p.	830.7000/pH	Pass (12-Feb-2014)
49310103		Wo, C. (2013) Glutaraldehyde Technical: Physical and Chemical Characteristics: Color, Physical State, Odor, Stability to Normal and Elevated Temperature, pH, UV/Visible Absorption, Boiling Point, Density/Relative Density, Dissociation Constant, Partition Coefficient and Water Solubility. Project Number: 34617, P804/TGAI, 120524/5H. Unpublished study prepared by Product Safety Laboratories. 38p.	830.7050/UV/Visible absorption	Pass (12-Feb-2014)
49310103		Wo, C. (2013) Glutaraldehyde Technical: Physical and Chemical Characteristics: Color, Physical State, Odor, Stability to Normal and Elevated Temperature, pH, UV/Visible Absorption, Boiling Point, Density/Relative Density, Dissociation Constant, Partition Coefficient and Water Solubility. Project Number: 34617, P804/TGAI, 120524/5H. Unpublished study prepared by Product Safety Laboratories. 38p.	830.7220/Boiling point/boiling range	Pass (12-Feb-2014)
49310103		Wo, C. (2013) Glutaraldehyde Technical: Physical and Chemical Characteristics: Color, Physical State, Odor, Stability to Normal and Elevated Temperature, pH, UV/Visible Absorption, Boiling Point, Density/Relative Density, Dissociation Constant, Partition Coefficient and Water Solubility. Project Number: 34617, P804/TGAI, 120524/5H. Unpublished study prepared by Product Safety Laboratories. 38p.	830.7300/Density/relative density	Pass (12-Feb-2014)
49310103		Wo, C. (2013) Glutaraldehyde Technical: Physical and Chemical Characteristics: Color, Physical State, Odor, Stability to Normal and Elevated Temperature, pH, UV/Visible Absorption, Boiling Point, Density/Relative Density, Dissociation Constant, Partition Coefficient and Water Solubility. Project Number: 34617, P804/TGAI, 120524/5H. Unpublished study prepared by Product Safety Laboratories. 38p.	830.7370/Dissociation constants in water	Pass (12-Feb-2014)
49310103		Wo, C. (2013) Glutaraldehyde Technical: Physical and Chemical Characteristics: Color, Physical State, Odor, Stability to Normal and Elevated Temperature, pH, UV/Visible Absorption, Boiling Point, Density/Relative Density, Dissociation Constant, Partition Coefficient and Water Solubility. Project Number: 34617, P804/TGAI, 120524/5H. Unpublished study prepared by Product Safety Laboratories. 38p.	830.7550/Partition coefficient (n-octanol/water), shake flask method	Pass (12-Feb-2014)
49310103		Wo, C. (2013) Glutaraldehyde Technical: Physical and Chemical Characteristics: Color, Physical State, Odor, Stability to Normal and Elevated Temperature, pH, UV/Visible Absorption, Boiling Point, Density/Relative Density, Dissociation Constant, Partition Coefficient and Water Solubility. Project Number: 34617, P804/TGAI, 120524/5H. Unpublished study prepared by Product Safety Laboratories. 38p.	830.7840/Water solubility: Column elution method, shake flask method	Pass (12-Feb-2014)

DP#: (419156)

*** Studies Sent for Review ***

Decision#: (487386)

MRID	MRID Status	Citation Reference	Guideline	86-5 Status
49310104		Cage, S. (2012) Glutaraldehyde Technical: Vapour Pressure. Project Number: MIB0029, 1107/2009. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 18p.	830.7950/Vapor pressure	Pass (12-Feb-2014)

Lantz, Tracy

From: Oslosky, Stanley <Stanley.Oslosky@Weatherford.com>
Sent: Monday, April 21, 2014 4:58 PM
To: Lantz, Tracy
Subject: RE: 59106-I 10 day letter
Attachments: BC G50 Deficiency response compiled docx..pdf; CoverLetter_BC G50.pdf; Detailed Chemistry_BC G50.pdf; Transmittal Document BC G50.pdf; Waiver Request Chemistry_Vol 2_BC G50.pdf

Categories: Red Category

Tracy,

This is an e-mail copy of the documents in response to the e-mail below. I have included, for convenience a compiled copy of the total submission as one document as well as each document individually as a separate pdf. As stated in the cover letter a copy of the viscosity study is expected by the end of the week and to you by the 28th.

Call me with any concerns

Stan Oslosky
Consultant to Weatherford
724-316-0689

-----Original Message-----

From: Lantz, Tracy [mailto:Lantz.Tracy@epa.gov]
Sent: Thursday, April 10, 2014 6:30 PM
To: Oslosky, Stanley
Cc: Swindell, Marshall
Subject: FW: 59106-I 10 day letter

Please confirm that you have received this correspondence.

Please see the attached letter signed by Marshall Swindell.
The text of this letter is repeated below.

OPP Decision Number: 487386
EPA Reg. Number: 59106-I
Product Name: BioClear G50
EPA Receipt Date: February 3, 2014
EPA Company Number: 59106
Company Name: Clearwater International LLC d/b/a Weatherford Engineered Chemistry

Stan Oslosky
Consultant to Weatherford
2000 St. James Place, 7th Floor
Houston, TX 77056

Dear Mr. Oslosky:

The Agency has completed its preliminary technical screening of your application pursuant to Section 33(f)(4)(B)(i)(II) of the Federal Insecticide, Fungicide, and Rodenticide (FIFRA) Act, as amended by the Pesticide Registration Improvement

Extension Act. The Agency has determined that your application has not passed the preliminary technical screen and therefore is subject to rejection if the application is not corrected.

The submission has failed the Technical Screen for the following reasons:

You have indicated that this product is a me-too of 464-691. Based on the formulation submitted for this product, BioClear G50 is NOT a me-too of 464-691.

The following chemistry guidelines have not been addressed. These guideline must be addressed in order for EPA to continue the review of this application: 830.1900, 830.6314, 830.6315, 830.6316, 830.6317, 830.6319, 830.6320, and 830.7100. You may indicate that the data associated with 830.6317 and 830.6320 will be submitted for review at a later date.

In order for the review of your product to continue, you will need to correct your application by addressing the item(s) listed above within 10 business days of the date you received this letter. Corrections must be received by EPA by the 10th business day. EPA recommends sending your complete set of corrections by email to the contact listed below to ensure they are timely received. If studies or confidential information are being submitted by mail, a complete courtesy copy received by email by the deadline will be considered timely. If you cannot correct the application [or do not respond] within 10 business days, your application will be rejected.

At this time you could also choose to withdraw your application. If you have questions, please contact Marshall Swindell at Swindell.marshall@epa.gov or (703) 308-6341 or Tracy Lantz at Lantz.tracy@epa.gov or (703) 308-6415.

Tracy Lantz
Antimicrobials Division
Office of Pesticide Programs
Environmental Protection Agency
(703) 308-6415
Lantz.tracy@epa.gov

-----Original Message-----

From: EZTech_Printer [mailto:EZTek@epa.gov]
Sent: Thursday, April 10, 2014 6:22 PM
To: Lantz, Tracy
Subject: 59106-I 10 day letter

Please open the attached document. This document was digitally sent to you using an HP Digital Sending device. This message may contain confidential and privileged information. If it has been sent to you in error, please reply to advise the sender of the error and then immediately delete it. If you are not the intended recipient, do not read, copy, disclose or otherwise use this message. The sender disclaims any liability for such unauthorized use. PLEASE NOTE that all incoming e-mails sent to Weatherford e-mail accounts will be archived and may be scanned by us and/or by external service providers to detect and prevent threats to our systems, investigate illegal or inappropriate behavior, and/or eliminate unsolicited promotional e-mails (spam). This process could result in deletion of a legitimate e-mail before it is read by its intended recipient at our organization. Moreover, based on the scanning results, the full text of e-mails and attachments may be made available to Weatherford security and other personnel for review and appropriate action. If you have any concerns about this process, please contact us at dataprivacy@weatherford.com.



Weatherford[®]

Tracy Lantz
Antimicrobials Division
Office of Pesticide Programs
U. S. Environmental Protection Agency
One Potomac Yard, XX Floor, Room XXXX
2777 South Crystal Drive
Arlington, VA 22202

ATTENTION: Tracy Lantz (703) 308-6415
Product Management, Team 33

SUBJECT: Clearwater International, LLC d/b/a Weatherford Engineered Chemistry (59106)
BioClear G50
File symbol 59106-10

Dear Tracy;

In response to your e-mail dated 4-10-2014, please accept this response as outlined specifically below.
Your e-mail stated:

"The submission has failed the Technical Screen for the following reasons: You have indicated that this product is a me-too of 464-691. Based on the formulation submitted for this product, BioClear G50 is NOT a me-too of 464-691.

The following chemistry guidelines have not been addressed. These guidelines must be addressed in order for EPA to continue the review of this application: 830.1900, 830.6314, 830.6315, 830.6316, 830.6317, 830.6319, 830.6320, and 830.7100. You may indicate that the data associated with 830.6317 and 830.6320 will be submitted for review at a later date."

In the enclosed document entitled, *"Detailed Glutaraldehyde Chemistry"* I explain the pre-reaction chemistry of glutaraldehyde and its final composition to show equivalency to Registration number 464-491.

In the document also enclosed titled *"Waiver Request for Product Chemistry Data, BioClear G50, EPA registration number 59106-O"*: I have addressed the following: 830.1900, 830.6314, 830.6315, 830.6316, 830.6317, 830.6319, and 830.6320. For 830.7100 I have commissioned a viscosity determination, at an increased cost for an accelerated result. I expect to have a formal study completed by April 25, 2014. I will e-mail the viscosity study as soon as it is available. For test guideline numbers 830.6317 and 830.6320, concurrent studies are already in progress and an initial, preliminary result is included as an addendum to the above referenced Waiver request document.

Thank you for your assistance with this application and if you or your staff have any questions, please call me at 724-316-0689 or e-mail me at Stanley.oslosky@weatherford.com.

Sincerely,

Stan Oslosky
Consultant to Weatherford
Stanley.Oslosky@weatherford.com
Engineered Chemistry

TRANSMITTAL DOCUMENT

Transmittal Date: April 23, 2014
Name and Address of Submitter: CLEARWATER INTERNATIONAL LLC, D/B/A
WEATHERFORD ENGINEERED CHEMISTRY
HOUSTON, TX 77056
Regulatory action in support of which this package is submitted: *Information to support the registration of BioClear G50 (MUP)*
EPA Reg. No./File Symbol: 59106-I
Alternate test material name Glutaraldehyde

Administrative Materials

Transmittal Document
Cover Letter

Volume No.	Citation	MRID Number
1	Oslosky, 2014, Detailed Product Chemistry Data. Unpublished study by Clearwater International d/b/a Weatherford, 9 pages. With Confidential Attachment. (1 e-mail copy, 3 hard copies).	
2	Oslosky, 2014, Waiver Request for Product Chemistry Data. Unpublished study by Clearwater International d/b/a Weatherford, 7 pages. (1 e-mailed copy and 3 hard copies)	

Product: BioClear G50
Submitter Stan Oslosky
Company: CLEARWATER INTERNATIONAL LLC, D/B/A WEATHERFORD
ENGINEERED CHEMISTRY
Phone: 724-316-0689
E-mail: Stsnley.Oslosky@Weatherford.com

Lantz, Tracy

From: Oslosky, Stanley <Stanley.Oslosky@Weatherford.com>
Sent: Wednesday, April 30, 2014 5:05 PM
To: Lantz, Tracy
Subject: RE: 59106-I 10 day letter
Attachments: cover viscosity.pdf; complete viscosity report.pdf; Transmittal Document template--visc.pdf

Categories: Red Category

Hello Tracy,

I responded to all of the points on the email except viscosity. Attached is the final piece of data in response to the e-mail. A hard copy of the first response was also mailed via USmail. A hard copy of this viscosity study will also be placed in the mail.

Please note that study is titled "Glutaraldehyde: Physical and Chemical Characteristics: Viscosity" Glutaraldehyde technical in this case is chemically equivalent to BioClear G50 (59106-I) and BioClear 2500 (59106-O).

Regards,
Stan Oslosky
724-316-0689

-----Original Message-----

From: Lantz, Tracy [mailto:Lantz.Tracy@epa.gov]
Sent: Thursday, April 10, 2014 6:30 PM
To: Oslosky, Stanley
Cc: Swindell, Marshall
Subject: FW: 59106-I 10 day letter

Please confirm that you have received this correspondence.

Please see the attached letter signed by Marshall Swindell.
The text of this letter is repeated below.

OPP Decision Number: 487386
EPA Reg. Number: 59106-I
Product Name: BioClear G50
EPA Receipt Date: February 3, 2014
EPA Company Number: 59106
Company Name: Clearwater International LLC d/b/a Weatherford Engineered Chemistry

Stan Oslosky
Consultant to Weatherford
2000 St. James Place, 7th Floor
Houston, TX 77056

Dear Mr. Oslosky:

The Agency has completed its preliminary technical screening of your application pursuant to Section 33(f)(4)(B)(i)(II) of the Federal Insecticide, Fungicide, and Rodenticide (FIFRA) Act, as amended by the Pesticide Registration Improvement Extension Act. The Agency has determined that your application has not passed the preliminary technical screen and therefore is subject to rejection if the application is not corrected.

The submission has failed the Technical Screen for the following reasons:

You have indicated that this product is a me-too of 464-691. Based on the formulation submitted for this product, BioClear G50 is NOT a me-too of 464-691.

The following chemistry guidelines have not been addressed. These guideline must be addressed in order for EPA to continue the review of this application: 830.1900, 830.6314, 830.6315, 830.6316, 830.6317, 830.6319, 830.6320, and 830.7100. You may indicate that the data associated with 830.6317 and 830.6320 will be submitted for review at a later date.

In order for the review of your product to continue, you will need to correct your application by addressing the item(s) listed above within 10 business days of the date you received this letter. Corrections must be received by EPA by the 10th business day. EPA recommends sending your complete set of corrections by email to the contact listed below to ensure they are timely received. If studies or confidential information are being submitted by mail, a complete courtesy copy received by email by the deadline will be considered timely. If you cannot correct the application [or do not respond] within 10 business days, your application will be rejected.

At this time you could also choose to withdraw your application. If you have questions, please contact Marshall Swindell at Swindell.marshall@epa.gov or (703) 308-6341 or Tracy Lantz at Lantz.tracy@epa.gov or (703) 308-6415.

Tracy Lantz
Antimicrobials Division
Office of Pesticide Programs
Environmental Protection Agency
(703) 308-6415
Lantz.tracy@epa.gov

-----Original Message-----

From: EZTech_Printer [mailto:EZTek@epa.gov]
Sent: Thursday, April 10, 2014 6:22 PM
To: Lantz, Tracy
Subject: 59106-I 10 day letter

Please open the attached document. This document was digitally sent to you using an HP Digital Sending device. This message may contain confidential and privileged information. If it has been sent to you in error, please reply to advise the sender of the error and then immediately delete it. If you are not the intended recipient, do not read, copy, disclose or otherwise use this message. The sender disclaims any liability for such unauthorized use. PLEASE NOTE that all incoming e-mails sent to Weatherford e-mail accounts will be archived and may be scanned by us and/or by external service providers to detect and prevent threats to our systems, investigate illegal or inappropriate behavior, and/or eliminate unsolicited promotional e-mails (spam). This process could result in deletion of a legitimate e-mail before it is read by its intended recipient at our organization. Moreover, based on the scanning results, the full text of e-mails and attachments may be made available to Weatherford security and other personnel for review and appropriate action. If you have any concerns about this process, please contact us at dataprivacy@weatherford.com.



Weatherford®

Tracy Lantz
Antimicrobials Division
Office of Pesticide Programs
U. S. Environmental Protection Agency
One Potomac Yard, XX Floor, Room XXXX
2777 South Crystal Drive
Arlington, VA 22202

ATTENTION: Tracy Lantz (703) 308-6415
Product Management, Team 33

SUBJECT: Clearwater International, LLC d/b/a Weatherford Engineered Chemistry (59106)
BioClear G50 and BioClear 2500
File symbols: 59106-I and 59106-O

Dear Tracy;

In response to your e-mail dated 4-10-2014, please accept this additional study responsive Guideline 830.7100, the remaining outstanding data requirement.

I previously responded to all of the points on the email except viscosity. Attached is that final study.

Please note that study is titled "Glutaraldehyde: Physical and Chemical Characteristics: Viscosity" Glutaraldehyde technical in this case is chemically equivalent to BioClear G50 (59106-I) and BioClear 2500 (59106-O).

Thank you for your assistance with this application and if you or your staff have any questions, please call me at 724-316-0689 or e-mail me at Stanley.oslosky@weatherford.com.

Sincerely,

Stan Oslosky
Consultant to Weatherford □
Stanley.Oslosky@weatherford.com

Engineered Chemistry

Weatherford
2000 St. James Place
Houston, Texas 77056
USA

+1.713.968.4000
+1.713.969.2401 Fax

www.weatherford.com

TRANSMITTAL DOCUMENT

Transmittal Date: April 30, 2014
Name and Address of Submitter: CLEARWATER INTERNATIONAL LLC, D/B/A
WEATHERFORD ENGINEERED CHEMISTRY
HOUSTON, TX 77056
Regulatory action in support of which this package is submitted: *Information to support the registration of BioClear G50 (MUP)*
EPA Reg. No./File Symbol: 59106-I
Alternate test material name Glutaraldehyde

Administrative Materials

Transmittal Document
Cover Letter

Volume No.	Citation	MRID Number
1	Zehr, April 30, 2014; Glutaraldehyde Technical: Physical and Chemical Characteristics: Viscosity. Unpublished study by Clearwater International d/b/a Weatherford, 7 pages. (1 e-mailed copy and 3 hard)	

Product: BioClear G50
Submitter Stan Oslosky
Company: CLEARWATER INTERNATIONAL LLC, D/B/A WEATHERFORD
ENGINEERED CHEMISTRY
Phone: 724-316-0689
E-mail: Stsnley.Oslosky@Weatherford.com

DATA PACKAGE BEAN SHEET

Date: 03-Apr-2014

Page 1 of 2

Decision #: 487386

DP #: (419156)

PRIA

Parent DP #:

Submission #: 947069

E-Sub #:

*** Registration Information ***

Registration: 59106-I - BIO CLEAR G50

Company: 59106 - CLEARWATER INTERNATIONAL, LLC

Risk Manager: RM 33 - Marshall Swindell - (703) 308-6341 Room# PY1 S-8828

Risk Manager Reviewer: Tracy Lantz TLANTZ

Sent Date:

PRIA Due Date: 24-Jul-2014

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (A532) UNREGISTERED SOURCE OF ACTIVE INGREDIENT;NEW PRODUCT;CITE-ALL DAT

Ingredients: 043901, Glutaraldehyde(51.1%)

*** Data Package Information ***

Expedite: ☒ Yes ☐ No

Date Sent: 03-Apr-2014

Due Back:

DP Ingredient: 043901, Glutaraldehyde

DP Title: Chemistry Data Review

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: AD / PSB

Last Possible Science Due Date: 24-Jun-2014

Team Name: CTT

Science Due Date:

Reviewer Name:

Chris J.

4/3
4/4/14

Sub Data Package Due Date:

Contractor Name:

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

Can be printed on its own page

Package Instructions ***

† this information on 4/1/14.
screen by Wednesday, 4/9
11-04

MRID	MRID Status	Citation Reference	Guideline	86-5 Status
49310101		Oslosky, S. (2014) Product Chemistry Data: Part A: (Bio Clear 1000). Project Number: G50. Unpublished study prepared by Clearwater International, LLC. 24p.	830.1550/Product Identity and composition	Pass (12-Feb-2014)
49310101		Oslosky, S. (2014) Product Chemistry Data: Part A: (Bio Clear 1000). Project Number: G50. Unpublished study prepared by Clearwater International, LLC. 24p.	830.1600/Description of materials used to produce the product	Pass (12-Feb-2014)
49310101		Oslosky, S. (2014) Product Chemistry Data: Part A: (Bio Clear 1000). Project Number: G50. Unpublished study prepared by Clearwater International, LLC. 24p.	830.1620/Description of production process	Pass (12-Feb-2014)
49310101		Oslosky, S. (2014) Product Chemistry Data: Part A: (Bio Clear 1000). Project Number: G50. Unpublished study prepared by Clearwater International, LLC. 24p.	830.1670/Discussion of formation of impurities	Pass (12-Feb-2014)
49310101		Oslosky, S. (2014) Product Chemistry Data: Part A: (Bio Clear 1000). Project Number: G50. Unpublished study prepared by Clearwater International, LLC. 24p.	830.1700/Preliminary analysis	Pass (12-Feb-2014)
49310101		Oslosky, S. (2014) Product Chemistry Data: Part A: (Bio Clear 1000). Project Number: G50. Unpublished study prepared by Clearwater International, LLC. 24p.	830.1750/Certified limits	Pass (12-Feb-2014)
49310101		Oslosky, S. (2014) Product Chemistry Data: Part A: (Bio Clear 1000). Project Number: G50. Unpublished study prepared by Clearwater International, LLC. 24p.	830.1800/Enforcement analytical method	Pass (12-Feb-2014)
49310102		Valla, F. (2013) Glutaraldehyde Technical: Preliminary Analysis. Project Number: 34616, P809, 120418/5H. Unpublished study prepared by Eurofins/Product Safety Laboratories. 25p.	830.1700/Preliminary analysis	Pass (12-Feb-2014)
49310103		Wo, C. (2013) Glutaraldehyde Technical: Physical and Chemical Characteristics: Color, Physical State, Odor, Stability to Normal and Elevated Temperature, pH, UV/Visible Absorption, Boiling Point, Density/Relative Density, Dissociation Constant, Partition Coefficient and Water Solubility. Project Number: 34617, P804/TGAI, 120524/5H. Unpublished study prepared by Product Safety Laboratories. 38p.	830.6302/Color	Pass (12-Feb-2014)
49310103		Wo, C. (2013) Glutaraldehyde Technical: Physical and Chemical Characteristics: Color, Physical State, Odor, Stability to Normal and Elevated Temperature, pH, UV/Visible Absorption, Boiling Point, Density/Relative Density, Dissociation Constant, Partition Coefficient and Water Solubility. Project Number: 34617, P804/TGAI, 120524/5H. Unpublished study prepared by Product Safety Laboratories. 38p.	830.6303/Physical state	Pass (12-Feb-2014)
49310103		Wo, C. (2013) Glutaraldehyde Technical: Physical and Chemical Characteristics: Color, Physical State, Odor, Stability to Normal and Elevated Temperature, pH, UV/Visible Absorption, Boiling Point, Density/Relative Density, Dissociation Constant, Partition Coefficient and Water Solubility. Project Number: 34617, P804/TGAI, 120524/5H. Unpublished study prepared by Product Safety Laboratories. 38p.	830.6304/Odor	Pass (12-Feb-2014)
49310103		Wo, C. (2013) Glutaraldehyde Technical: Physical and Chemical Characteristics: Color, Physical State, Odor, Stability to Normal and Elevated Temperature, pH, UV/Visible Absorption, Boiling Point, Density/Relative Density, Dissociation Constant, Partition Coefficient and Water Solubility. Project Number: 34617, P804/TGAI, 120524/5H. Unpublished study prepared by Product Safety Laboratories. 38p.	830.6313/Stability to normal and elevated temperatures, metals, and metal ions	Pass (12-Feb-2014)

DP#: (419156)

*** Studies Sent for Review ***

Decision#: (487386)

MRID	MRID Status	Citation Reference	Guideline	86-5 Status
49310104		Cage, S. (2012) Glutaraldehyde Technical: Vapour Pressure. Project Number: MIB0029, 1107/2009. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 18p.	830.7950/Vapor pressure	Pass (12-Feb-2014)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

May 06, 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

CLEARWATER INTERNATIONAL, LLC
2000 ST. JAMES PLACE, 7TH FLOOR
HOUSTON, TX 77056

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 02-MAY-14. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.



Receipt for Section 3

S: 951727

Milestone Email:

Regulatory Type: Product Registration - Section 3

Resubmission: ☒ Yes ☐ No

Application Type: New Registration

Fee For Service: ☐ Yes ☒ No

Billable: ☐ Yes ☒ No

Company: 59106 CLEARWATER INTERNATIONAL, LLC

V

Risk Manager: Antimicrobials Division, Risk Management Team 33

Product #: 59106-I

Product Name: BIO CLEAR G50

Override:

Me Too
Section3: 464-691

Me Too Product
Name: UCARCIDE 250 ANTIMICROBIAL

Application Date: 02-May-2014



OPP Rec'd Date: 02-May-2014



Front End Date: 05-May-2014



Risk Manager Send Date: 05-May-2014



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

response to EPA email of 4/10/14: product chemistry data waiver request

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Des

Study

View/Edit



49375200

Weatherford

Tracy Lantz
Antimicrobials Division
Office of Pesticide Programs
U. S. Environmental Protection Agency
One Potomac Yard, XX Floor, Room XXXX
2777 South Crystal Drive
Arlington, VA 22202

ATTENTION: Tracy Lantz (703) 308-6415
Product Management, Team 33

SUBJECT: Clearwater International, LLC d/b/a Weatherford Engineered Chemistry (59106)
BioClear G50
File symbol 59106-I

Dear Tracy;

In response to your e-mail dated 4-10-2014, please accept this response as outlined specifically below.
Your e-mail stated:

"The submission has failed the Technical Screen for the following reasons: You have indicated that this product is a me-too of 464-691. Based on the formulation submitted for this product, BioClear G50 is NOT a me-too of 464-691.

The following chemistry guidelines have not been addressed. These guidelines must be addressed in order for EPA to continue the review of this application: 830.1900, 830.6314, 830.6315, 830.6316, 830.6317, 830.6319, 830.6320, and 830.7100. You may indicate that the data associated with 830.6317 and 830.6320 will be submitted for review at a later date."

In the enclosed document entitled, *"Detailed Glutaraldehyde Chemistry"* I explain the pre-reaction chemistry of glutaraldehyde and its final composition to show equivalency to Registration number 464-491.

In the document also enclosed titled *"Waiver Request for Product Chemistry Data, BioClear G50, EPA registration number 59106-O"*: I have addressed the following: 830.1900, 830.6314, 830.6315, 830.6316, 830.6317, 830.6319, and 830.6320. For 830.7100 I have commissioned a viscosity determination, at an increased cost for an accelerated result. I expect to have a formal study completed by April 25, 2014. I will e-mail the viscosity study as soon as it is available. For test guideline numbers 830.6317 and 830.6320, concurrent studies are already in progress and an initial, preliminary result is included as an addendum to the above referenced Waiver request document.

Thank you for your assistance with this application and if you or your staff have any questions, please call me at 724-316-0689 or e-mail me at Stanley.oslosky@weatherford.com.

Sincerely,

Stan Oslosky
Consultant to Weatherford
Stanley.Oslosky@weatherford.com
Engineered Chemistry

TRANSMITTAL DOCUMENT

Transmittal Date: April 23, 2014
Name and Address of Submitter: CLEARWATER INTERNATIONAL LLC, D/B/A
WEATHERFORD ENGINEERED CHEMISTRY
HOUSTON, TX 77056
Regulatory action in support of which this package is submitted: *Information to support the registration of BioClear G50 (MUP)*
EPA Reg. No./File Symbol: 59106-I
Alternate test material name Glutaraldehyde

Administrative Materials

Transmittal Document
Cover Letter

Volume No.	Citation	MRID Number
1	Oslosky, 2014, Detailed Product Chemistry Data. Unpublished study by Clearwater International d/b/a Weatherford, 9 pages. With Confidential Attachment. (1 e-mail copy, 3 hard copies).	49375201
2	Oslosky, 2014, Waiver Request for Product Chemistry Data. Unpublished study by Clearwater International d/b/a Weatherford, 7 pages. (1 e-mailed copy and 3 hard copies)	49375202

Product: BioClear G50
Submitter: Stan Oslosky
Company: CLEARWATER INTERNATIONAL LLC, D/B/A WEATHERFORD
ENGINEERED CHEMISTRY
Phone: 724-316-0689
E-mail: Stsnley.Oslosky@Weatherford.com

DATA PACKAGE BEAN SHEET

Date: 05-Jun-2014

Page 1 of 2

Decision #: 487386

DP #: (420708)

PRIA

Parent DP #:

Submission #: 952214

E-Sub #:

*** Registration Information ***

Registration: **59106-I - BIO CLEAR G50**

Company: 59106 - CLEARWATER INTERNATIONAL, LLC

Risk Manager:

Risk Manager Reviewer: Tracy Lantz TLANTZ

Sent Date: 13-May-2014

PRIA Due Date: 24-Jul-2014

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (A532) UNREGISTERED SOURCE OF ACTIVE INGREDIENT;NEW PRODUCT;CITE-ALL DAT

Ingredients: 043901, Glutaraldehyde(51.1%)

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 05-Jun-2014

Due Back:

DP Ingredient: 043901, Glutaraldehyde

DP Title: Additional chemistry data in reply to screen

CSF Included: ☐ Yes ☒ No

Label Included: ☐ Yes ☒ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: AD / PSB

Last Possible Science Due Date: 24-Jun-2014

Team Name: CTT

Science Due Date:

Reviewer Name:

Sub Data Package Due Date:

Contractor Name:

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

Can be printed on its own page

*** Data Package Instructions ***

Please review the additional chemistry study, MRID 49375201 in response to the chemistry screen deficiencies

DP#: (420708)

*** Studies Sent for Review ***

Decision#: (487386)

MRID	MRID Status	Citation Reference	Guideline	86-5 Status
49375201		Oslosky, S (2014) Detailed Glutaraldehyde Chemistry. Unpublished study prepared by Clearwater International, Llc. 9p.		Pass (09-May-2014)

Lantz, Tracy

From: Oslosky, Stanley <Stanley.Oslosky@Weatherford.com>
Sent: Monday, April 21, 2014 4:58 PM
To: Lantz, Tracy
Subject: RE: 59106-I 10 day letter
Attachments: BC G50 Deficiency response compiled docx..pdf; CoverLetter_BC G50.pdf; Detailed Chemistry_BC G50.pdf; Transmittal Document BC G50.pdf; Waiver Request Chemistry_Vol 2_BC G50.pdf

Categories: Red Category

*Sent to Joan 4/22
or Chris V. ?*

Tracy,

This is an e-mail copy of the documents in response to the e-mail below. I have included, for convenience a compiled copy of the total submission as one document as well as each document individually as a separate pdf. As stated in the cover letter a copy of the viscosity study is expected by the end of the week and to you by the 28th.

Call me with any concerns

Stan Oslosky
Consultant to Weatherford
724-316-0689

-----Original Message-----

From: Lantz, Tracy [mailto:Lantz.Tracy@epa.gov]
Sent: Thursday, April 10, 2014 6:30 PM
To: Oslosky, Stanley
Cc: Swindell, Marshall
Subject: FW: 59106-I 10 day letter

Please confirm that you have received this correspondence.

Please see the attached letter signed by Marshall Swindell.
The text of this letter is repeated below.

OPP Decision Number: 487386
EPA Reg. Number: 59106-I
Product Name: BioClear G50
EPA Receipt Date: February 3, 2014
EPA Company Number: 59106
Company Name: Clearwater International LLC d/b/a Weatherford Engineered Chemistry

Stan Oslosky
Consultant to Weatherford
2000 St. James Place, 7th Floor
Houston, TX 77056

Dear Mr. Oslosky:

The Agency has completed its preliminary technical screening of your application pursuant to Section 33(f)(4)(B)(i)(II) of the Federal Insecticide, Fungicide, and Rodenticide (FIFRA) Act, as amended by the Pesticide Registration Improvement

Extension Act. The Agency has determined that your application has not passed the preliminary technical screen and therefore is subject to rejection if the application is not corrected.

The submission has failed the Technical Screen for the following reasons:

You have indicated that this product is a me-too of 464-691. Based on the formulation submitted for this product, BioClear G50 is NOT a me-too of 464-691.

The following chemistry guidelines have not been addressed. These guideline must be addressed in order for EPA to continue the review of this application: 830.1900, 830.6314, 830.6315, 830.6316, 830.6317, 830.6319, 830.6320, and 830.7100. You may indicate that the data associated with 830.6317 and 830.6320 will be submitted for review at a later date.

In order for the review of your product to continue, you will need to correct your application by addressing the item(s) listed above within 10 business days of the date you received this letter. Corrections must be received by EPA by the 10th business day. EPA recommends sending your complete set of corrections by email to the contact listed below to ensure they are timely received. If studies or confidential information are being submitted by mail, a complete courtesy copy received by email by the deadline will be considered timely. If you cannot correct the application [or do not respond] within 10 business days, your application will be rejected.

At this time you could also choose to withdraw your application. If you have questions, please contact Marshall Swindell at Swindell.marshall@epa.gov or (703) 308-6341 or Tracy Lantz at Lantz.tracy@epa.gov or (703) 308-6415.

Tracy Lantz
Antimicrobials Division
Office of Pesticide Programs
Environmental Protection Agency
(703) 308-6415
Lantz.tracy@epa.gov

-----Original Message-----

From: EZTech_Printer [mailto:EZTek@epa.gov]
Sent: Thursday, April 10, 2014 6:22 PM
To: Lantz, Tracy
Subject: 59106-I 10 day letter

Please open the attached document. This document was digitally sent to you using an HP Digital Sending device. This message may contain confidential and privileged information. If it has been sent to you in error, please reply to advise the sender of the error and then immediately delete it. If you are not the intended recipient, do not read, copy, disclose or otherwise use this message. The sender disclaims any liability for such unauthorized use. PLEASE NOTE that all incoming e-mails sent to Weatherford e-mail accounts will be archived and may be scanned by us and/or by external service providers to detect and prevent threats to our systems, investigate illegal or inappropriate behavior, and/or eliminate unsolicited promotional e-mails (spam). This process could result in deletion of a legitimate e-mail before it is read by its intended recipient at our organization. Moreover, based on the scanning results, the full text of e-mails and attachments may be made available to Weatherford security and other personnel for review and appropriate action. If you have any concerns about this process, please contact us at dataprivacy@weatherford.com.

Lantz, Tracy

From: Lewis, Susan
Sent: Tuesday, April 22, 2014 6:00 PM
To: Lantz, Tracy
Cc: Hebert, John
Subject: Re: ATP update for CSPA and held in abeyance letter

Tracy, update on website, next priority For testing,

From: Lantz, Tracy
Sent: Tuesday, April 22, 2014 3:35:56 PM
To: Lewis, Susan
Cc: Hebert, John
Subject: RE: ATP update for CSPA and held in abeyance letter

I will try to work on both of these items tomorrow.
Should be able to get a couple of slides to you by Thursday.
I have a scheduled medical appointment tomorrow so will be away from my alternative work place most of the day.
Any particular topics/key points that you would like to include on ATP to the CSPA audience?

Tracy Lantz

Antimicrobials Division
Office of Pesticide Programs
Environmental Protection Agency
(703) 308-6415
Lantz.tracy@epa.gov

From: Lewis, Susan
Sent: Tuesday, April 22, 2014 1:54 PM
To: Lantz, Tracy
Cc: Hebert, John
Subject: ATP update

Tracy, I'm speaking at the CSPA meeting in Chicago. Could you provide a few power point slides by this Thursday on ATP testing. Also, was thinking we need to get out the letters to those companies held in abeyance. Can you please give me a timeline. Thanks

Susan Lewis
Director, Antimicrobial Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
703-308-8009



Weatherford[®]

Tracy Lantz
Antimicrobials Division
Office of Pesticide Programs
U. S. Environmental Protection Agency
One Potomac Yard, XX Floor, Room XXXX
2777 South Crystal Drive
Arlington, VA 22202

ATTENTION: Tracy Lantz (703) 308-6415
Product Management, Team 33

SUBJECT: Clearwater International, LLC d/b/a Weatherford Engineered Chemistry (59106)
BioClear G50
File symbol 59106-I

Dear Tracy;

In response to your e-mail dated 4-10-2014, please accept this response as outlined specifically below.
Your e-mail stated:

"The submission has failed the Technical Screen for the following reasons: You have indicated that this product is a me-too of 464-691. Based on the formulation submitted for this product, BioClear G50 is NOT a me-too of 464-691.

The following chemistry guidelines have not been addressed. These guidelines must be addressed in order for EPA to continue the review of this application: 830.1900, 830.6314, 830.6315, 830.6316, 830.6317, 830.6319, 830.6320, and 830.7100. You may indicate that the data associated with 830.6317 and 830.6320 will be submitted for review at a later date."

In the enclosed document entitled, *"Detailed Glutaraldehyde Chemistry"* I explain the pre-reaction chemistry of glutaraldehyde and its final composition to show equivalency to Registration number 464-491.

In the document also enclosed titled *"Waiver Request for Product Chemistry Data, BioClear G50, EPA registration number 59106-O"*: I have addressed the following: 830.1900, 830.6314, 830.6315, 830.6316, 830.6317, 830.6319, and 830.6320. For 830.7100 I have commissioned a viscosity determination, at an increased cost for an accelerated result. I expect to have a formal study completed by April 25, 2014. I will e-mail the viscosity study as soon as it is available. For test guideline numbers 830.6317 and 830.6320, concurrent studies are already in progress and an initial, preliminary result is included as an addendum to the above referenced Waiver request document.

Thank you for your assistance with this application and if you or your staff have any questions, please call me at 724-316-0689 or e-mail me at Stanley.oslosky@weatherford.com.

Sincerely,

Stan Oslosky
Consultant to Weatherford
Stanley.Oslosky@weatherford.com
Engineered Chemistry

TRANSMITTAL DOCUMENT

Transmittal Date: April 23, 2014
Name and Address of Submitter: CLEARWATER INTERNATIONAL LLC, D/B/A WEATHERFORD ENGINEERED CHEMISTRY
HOUSTON, TX 77056
Regulatory action in support of which this package is submitted: *Information to support the registration of BioClear G50 (MUP)*
EPA Reg. No./File Symbol: 59106-I
Alternate test material name Glutaraldehyde

Administrative Materials

Transmittal Document
Cover Letter

Volume No.	Citation	MRID Number
1	Oslosky, 2014, Detailed Product Chemistry Data. Unpublished study by Clearwater International d/b/a Weatherford, 9 pages. With Confidential Attachment. (1 e-mail copy, 3 hard copies).	
2	Oslosky, 2014, Waiver Request for Product Chemistry Data. Unpublished study by Clearwater International d/b/a Weatherford, 7 pages. (1 e-mailed copy and 3 hard copies)	

Product: BioClear G50
Submitter Stan Oslosky
Company: CLEARWATER INTERNATIONAL LLC, D/B/A WEATHERFORD ENGINEERED CHEMISTRY
Phone: 724-316-0689
E-mail: Stsnley.Oslosky@Weatherford.com

Volume 2

Study Title

Waiver Request for Product Chemistry Data
BioClear G50
EPA registration # 59106-1

Data Requirement
Chemistry

Series 830.1900, 830.6314, 830.6315, 830.6316, 830.6317, 830.6319,
830.6320

Author

Stan Oslosky

Completed

January 27, 2014
Revised 4-14-2014

CLEARWATER INTERNATIONAL LLC,
D/B/A WEATHERFORD ENGINEERED CHEMISTRY, HOUSTON, TX 77056

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA section 10(d)(1)(A), (B), or (C).

Company: CLEARWATER INTERNATIONAL LLC,
D/B/A WEATHERFORD ENGINEERED CHEMISTRY,
HOUSTON, TX 77056

Company Agent: Stan Oslosky
Consultant to Weatherford
Ph. 724-317-0689



Signature: _____

Date: April 14,, 2014 _____

Good Laboratory Practice Statement

The enclosed studies do not meet the requirements of 40 CFR 160. Since the material contained here is not a study, but a compilation of waivers, Good Laboratory Practices are not applicable.

Submitter: Stan Oslosky

Title: Consultant to Weatherford



Signature:

Date: April 14, 2014

Study Director Stan Oslosky

Title: Consultant to Weatherford



Signature:

Date: April 14, 2014

Sponsor Stan Oslosky

Title: Consultant to Weatherford



Signature:

Date: April 14, 2014

Waivers
Series 830.1900, 830.6314, 830.6315, 830.6316, 830.6317, 830.6319,
830.6320

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Guideline Number	Data Requirements	Location
830.1900	Submittal of samples	Page 5 (Waiver)
830.6314	Oxidation/Reduction	Page 5 (Waiver)
830.6315	Flammability	Page 5 (Waiver)
830.6316	Explodability	Page 5 (Waiver)
830.6317	Storage Stability (see Addendum)	Page 5(Waiver)
830.6319	Miscibility	Page 6 (Waiver)
830.6320	Corrosion characteristics	Page 6 (Waiver)
830.6317	Storage Stability; initial test Preliminary results	Page 7

Chemistry Waiver Requests

BioClear G50 Antimicrobial

Glutaraldehyde

EPA registration # 59106-O

830.1900	Submittal of samples - WAIVER REQUEST
-----------------	--

Samples will be submitted to the EPA upon request.

830.6314	Oxidation/Reduction - WAIVER REQUEST
-----------------	---

BioClear G50 Antimicrobial contains no oxidizing or reducing agents. A waiver based on 40 CFR 158.310, footnote 13 is requested.

830.6315	Flammability - WAIVER REQUEST
-----------------	--------------------------------------

BioClear G50 Antimicrobial contains no combustible liquids; it is aqueous solution of Glutaraldehyde. A waiver based on 40 CFR 158.310, footnote 14 is requested.

830.6316	Explodability - WAIVER REQUEST
-----------------	---------------------------------------

BioClear G50 Antimicrobial is not potentially explosive; it is an aqueous solution of Glutaraldehyde. A waiver based on 40 CFR 158.310, footnote 15 is requested.

830.6317	Storage Stability - WAIVER REQUEST
-----------------	---

The storage stability test for BioClear G50 Antimicrobial is not available at this time but is being conducted. The study will be submitted as soon as it is available. Expected completion date is February 2015.

830.6319 Miscibility - WAIVER REQUEST

BioClear G50 Antimicrobial is not an emulsifiable liquid that will be diluted in organic solvents. A waiver based on 40 CFR 158.310, footnote 16 is requested.

830.6320 Corrosion Characteristics- WAIVER REQUEST
--

The Corrosion Characteristics test for BioClear G50 Antimicrobial is not available at this time but is being conducted concurrently with the Storage stability. The study will be submitted as soon as it is available. It will be done concurrently and in combination with the storage stability. Expected completion date is February 2015.

Addendum: Preliminary initial results for Storage Stability study

Below is a summary of results for chemistry studies completed on the following product. Additional results will be e-mailed as your other studies are completed.

PRODUCT IDENTIFICATION: Glutaraldehyde Technical; Batch #: G-13092804

Spec. 50% (Spec. Range: 49.6% – 52.6%)

STORAGE STABILITY AND CORROSION CHARACTERISTICS

PSL Study number: 38342

Results: Composition of the test substance as determined by Product Safety Labs

Time:	Active	Result
Initial:	Glutaraldehyde	52.6%
3 months:		
6 months:		
9 months:		
12 months:		
18 months:		
24 months:		

This information represents an unaudited summary of the data. Additional relevant findings may be presented in the Draft/Final report(s), which will be forwarded to you as they are completed. If you would like to discuss these results, please contact our Study Director, Janie Zitomer at 732-438-5100 ext. 1544 or at JanieZitomer@ProductSafetyLabs.com. Thank you.

Ralph C. Iacuzio
Technical Writer
Product Safety Labs
2394 U.S. Highway 130
Dayton, NJ 08810 USA
732-438-5100 ext. 1554
RalphIacuzio@productsafetylabs.com

Lantz, Tracy

59106-I

From: Oslosky, Stanley <Stanley.Oslosky@Weatherford.com>
Sent: Wednesday, April 30, 2014 5:05 PM
To: Lantz, Tracy
Subject: ~~FW: 59106-I~~ 10 day letter
Attachments: cover viscosity.pdf; complete viscosity report.pdf; Transmittal Document template--visc.pdf

Categories: Red Category

Hello Tracy,

I responded to all of the points on the email except viscosity. Attached is the final piece of data in response to the e-mail. A hard copy of the first response was also mailed via USmail. A hard copy of this viscosity study will also be placed in the mail.

Please note that study is titled "Glutaraldehyde: Physical and Chemical Characteristics: Viscosity" Glutaraldehyde technical in this case is chemically equivalent to BioClear G50 (59106-I) and BioClear 2500 (59106-O).

Regards,
Stan Oslosky
724-316-0689

-----Original Message-----

From: Lantz, Tracy [mailto:Lantz.Tracy@epa.gov]
Sent: Thursday, April 10, 2014 6:30 PM
To: Oslosky, Stanley
Cc: Swindell, Marshall
Subject: FW: 59106-I 10 day letter

Please confirm that you have received this correspondence.

Please see the attached letter signed by Marshall Swindell.
The text of this letter is repeated below.

OPP Decision Number: 487386
EPA Reg. Number: 59106-I
Product Name: BioClear G50
EPA Receipt Date: February 3, 2014
EPA Company Number: 59106
Company Name: Clearwater International LLC d/b/a Weatherford Engineered Chemistry

Stan Oslosky
Consultant to Weatherford
2000 St. James Place, 7th Floor
Houston, TX 77056

Dear Mr. Oslosky:

The Agency has completed its preliminary technical screening of your application pursuant to Section 33(f)(4)(B)(i)(II) of the Federal Insecticide, Fungicide, and Rodenticide (FIFRA) Act, as amended by the Pesticide Registration Improvement Extension Act. The Agency has determined that your application has not passed the preliminary technical screen and therefore is subject to rejection if the application is not corrected.

The submission has failed the Technical Screen for the following reasons:

You have indicated that this product is a me-too of 464-691. Based on the formulation submitted for this product, BioClear G50 is NOT a me-too of 464-691.

The following chemistry guidelines have not been addressed. These guideline must be addressed in order for EPA to continue the review of this application: 830.1900, 830.6314, 830.6315, 830.6316, 830.6317, 830.6319, 830.6320, and 830.7100. You may indicate that the data associated with 830.6317 and 830.6320 will be submitted for review at a later date.

In order for the review of your product to continue, you will need to correct your application by addressing the item(s) listed above within 10 business days of the date you received this letter. Corrections must be received by EPA by the 10th business day. EPA recommends sending your complete set of corrections by email to the contact listed below to ensure they are timely received. If studies or confidential information are being submitted by mail, a complete courtesy copy received by email by the deadline will be considered timely. If you cannot correct the application [or do not respond] within 10 business days, your application will be rejected.

At this time you could also choose to withdraw your application. If you have questions, please contact Marshall Swindell at Swindell.marshall@epa.gov or (703) 308-6341 or Tracy Lantz at Lantz.tracy@epa.gov or (703) 308-6415.

Tracy Lantz
Antimicrobials Division
Office of Pesticide Programs
Environmental Protection Agency
(703) 308-6415
Lantz.tracy@epa.gov

-----Original Message-----

From: EZTech_Printer [mailto:EZTek@epa.gov]
Sent: Thursday, April 10, 2014 6:22 PM
To: Lantz, Tracy
Subject: 59106-I 10 day letter

Please open the attached document. This document was digitally sent to you using an HP Digital Sending device. This message may contain confidential and privileged information. If it has been sent to you in error, please reply to advise the sender of the error and then immediately delete it. If you are not the intended recipient, do not read, copy, disclose or otherwise use this message. The sender disclaims any liability for such unauthorized use. PLEASE NOTE that all incoming e-mails sent to Weatherford e-mail accounts will be archived and may be scanned by us and/or by external service providers to detect and prevent threats to our systems, investigate illegal or inappropriate behavior, and/or eliminate unsolicited promotional e-mails (spam). This process could result in deletion of a legitimate e-mail before it is read by its intended recipient at our organization. Moreover, based on the scanning results, the full text of e-mails and attachments may be made available to Weatherford security and other personnel for review and appropriate action. If you have any concerns about this process, please contact us at dataprivacy@weatherford.com.



Weatherford®

Tracy Lantz
Antimicrobials Division
Office of Pesticide Programs
U. S. Environmental Protection Agency
One Potomac Yard, XX Floor, Room XXXX
2777 South Crystal Drive
Arlington, VA 22202

ATTENTION: Tracy Lantz (703) 308-6415
Product Management, Team 33

SUBJECT: Clearwater International, LLC d/b/a Weatherford Engineered Chemistry (59106)
BioClear G50 and BioClear 2500
File symbols ~~59106-I~~ and ~~59106-O~~

Dear Tracy;

In response to your e-mail dated 4-10-2014, please accept this additional study responsive Guideline 830.7100, the remaining outstanding data requirement.

I previously responded to all of the points on the email except viscosity. Attached is that final study.

Please note that study is titled "Glutaraldehyde: Physical and Chemical Characteristics: Viscosity" Glutaraldehyde technical in this case is chemically equivalent to BioClear G50 (59106-I) and BioClear 2500 (59106-O).

Thank you for your assistance with this application and if you or your staff have any questions, please call me at 724-316-0689 or e-mail me at Stanley.oslosky@weatherford.com.

Sincerely,

Stan Oslosky
Consultant to Weatherford □
Stanley.Oslosky@weatherford.com

Engineered Chemistry

Weatherford
2000 St. James Place
Houston, Texas 77056
USA

+1.713.968.4000
+1.713.969.2401 Fax

www.weatherford.com

TRANSMITTAL DOCUMENT

Transmittal Date: April 30, 2014
Name and Address of Submitter: CLEARWATER INTERNATIONAL LLC, D/B/A
WEATHERFORD ENGINEERED CHEMISTRY
HOUSTON, TX 77056
Regulatory action in support of which this package is submitted: *Information to support the registration of BioClear G50 (MUP)*
EPA Reg. No./File Symbol: 59106-I
Alternate test material name Glutaraldehyde

Administrative Materials

Transmittal Document
Cover Letter

Volume No.	Citation	MRID Number
1	Zehr, April 30, 2014; Glutaraldehyde Technical: Physical and Chemical Characteristics: Viscosity. Unpublished study by Clearwater International d/b/a Weatherford, 7 pages. (1 e-mailed copy and 3 hard)	

Product: BioClear G50
Submitter Stan Oslosky
Company: CLEARWATER INTERNATIONAL LLC, D/B/A WEATHERFORD
ENGINEERED CHEMISTRY
Phone: 724-316-0689
E-mail: Stsnley.Oslosky@Weatherford.com

464-691 12/23/2008 12/23/2008

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



Office of Pesticide Programs

The Dow Chemical Company
1803 Building
Midland, Mi 48674

DEC 23 2008

Attention: Maureen Mikszta
Senior Regulatory Specialist

Subject: UCARCIDE 250 Antimicrobial
EPA Registration No. 464-691
Amendment Dated November 20, 2008

The amendment, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable.

- Minor Labeling Changes to the Directions For Use

A stamped copy of the "accepted" labeling is enclosed for your records.

If you have any questions concerning this letter, please contact Martha Terry at (703) 308-6217.

Sincerely

Marshall Swindell
Product Manager 33
Regulatory Management Branch 1
Antimicrobials Division (7510P)

Enclosure



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 464-691	2. EPA Product Manager M. Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) UCARCIDE 250 Antimicrobial	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) The Dow Chemical Company 1803 Building Midland, MI 48674 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Dow is submitting an amendment which includes minor labeling changes to the directions for use within an already registered use pattern category. Although PR Notice 98-10 permits this type of action via notification, Dow is submitting it as an amendment to obtain a stamped label. On 11/19/2008, Dow had a discussion with Marshall Swindell regarding label changes and the pending DCI for glutaraldehyde. At the conclusion of this discussion, there was an agreement that other label changes including container disposal statements and RED changes would be addressed when the DCI issues in 3Q 2009.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input checked="" type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 5 gallon, 55 gallon and bulk		5. Location of Label Directions <input checked="" type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph Paper, glued Stenciled				<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Maureen Mikszta		Title Senior Regulatory Specialist	
		Telephone No. (Include Area Code) 732-563-5586	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			
2. Signature 		3. Title Senior Regulatory Specialist	
4. Typed Name Maureen Mikszta		5. Date 11/20/08	
6. Date Application Received (Stamped)			



3 of 6

The Dow Chemical Company
171 River Road
Piscataway, NJ 08854
USA

November 20, 2008

Overnight Delivery

Document Processing Desk (Amend)
Office of Pesticides Programs (7504P)
Antimicrobials Division
U. S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Subject: UCARCIDE™ 250 Antimicrobial, EPA Reg. No. 464-691
Label Amendment

Dear Sir/Madam:

The Dow Chemical Company (Dow) is submitting an amendment to the registration for UCARCIDE™ 250 Antimicrobial, EPA Reg. No. 464-691. This amendment includes minor labeling changes to the directions for use within an already registered use pattern category. Although PR Notice 98-10 permits this type of action via notification, Dow is submitting it as an amendment to obtain a stamped label. For this type of amendment, there is no action code associated and therefore no fee is required.

On 11/19/2008, Dow had a discussion with Marshall Swindell regarding label changes and the pending DCI for glutaraldehyde. At the conclusion of this discussion, there was an agreement that other label changes including container disposal statements and RED changes would be addressed when the DCI issues in 3Q 2009.

Please find enclosed the following documentation in support of this application:

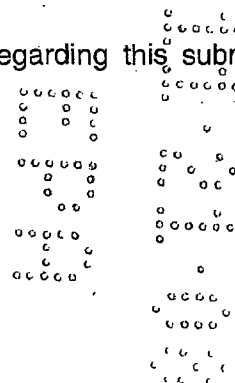
- Application Form, EPA Form 8570-1
- Certification with Respect to Citation of Data, EPA Form 8570-34
- (5) Draft Labels
- (1) Label highlighted with changes

Please contact me at 732-563-5586 with questions or comments regarding this submission.
Thank you for your assistance.

Sincerely,

Maureen Mikszta
Senior Regulatory Specialist
miksztm@dow.com

cc: Mr. Swindell, PM-33



UCARCIDE™ 250

ANTIMICROBIAL

FOR USE BY MANUFACTURERS FOR FORMULATING INDUSTRIAL BACTERICIDES AND PRESERVATIVES. FORMULATORS USING THIS PRODUCT ARE RESPONSIBLE FOR PROVIDING DATA FOR THE EPA REGISTRATION OF THEIR FORMULATED PRODUCTS.

Active Ingredient: Glutaraldehyde	50%
Inert Ingredients:	50%
Total	100%

KEEP OUT OF REACH OF CHILDREN DANGER FIRST AID

If swallowed:

- Call a poison control center or a doctor immediately for treatment advice.
- DO NOT INDUCE VOMITING.
- Do not give anything to drink.

If in eyes:

- Wash immediately and continuously with flowing water for at least 30 minutes.
- Remove contact lenses after the first 5 minutes and continue washing. Obtain prompt medical consultation, preferably from an ophthalmologist.
- Call a poison control center or a doctor immediately for treatment advice.

If on skin or clothing:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or a doctor for treatment advice.

If inhaled:

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, and then give artificial respiration, preferably mouth-to-mouth if possible.
- Call a poison control center or a doctor for further treatment advice.

NOTE TO PHYSICIAN: Aspiration may cause lung damage. Probable mucosal damage may contraindicate the use of gastric lavage.

Have the MSDS and, if available, the product container or label with you when calling a poison control center or a doctor, or going for treatment.

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

Produced for:



The Dow Chemical Company

Midland, Michigan 48674 U.S.A.

(989)636-4400

®TM Trademark of The Dow Chemical Company

("Dow") or an affiliated company of Dow

Made in U.S.A.

EPA Reg. No. 464-691

EPA Est. No. 10352-WV-2 (A); 464-WV-1 (B)

(A) 5 gallon pails in pallets; all drums; bulk

(B) Samples, 5 gallon pails less than pallet

(J 11/08)
PE1108

Net Contents: 5, 55 gallons or Bulk

CONTAINER SIZE TO TE	CONTAINER SIZE 55 GALLONS	CONTAINER SIZE 5 GALLONS	SHIPPING NAME	CORROSIVE LIQUID, ACIDIC, ORGANIC, N.O.S. (CONTAINS GLUTARALDEHYDE)	
26.2 GALLONS					
2,446 POUNDS NET WEIGHT	500 POUNDS NET WEIGHT	46 POUNDS NET WEIGHT	HAZARD CLASS 8	ID NUMBER UN3265	PGII

IN CASE OF AN EMERGENCY endangering life or property involving this product, call collect (989)636-4400.

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

DANGER

KEEP OUT OF REACH OF CHILDREN

Corrosive. Causes irreversible eye damage. Causes skin burns. Harmful if inhaled. May be fatal if swallowed. Harmful if absorbed through the skin. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Causes asthmatic signs and symptoms in hyper-reactive individuals.

Do not get in eyes, on skin, on clothing.
Avoid breathing vapor. Do not swallow.
Wear goggles, protective clothing, and butyl or nitrile gloves.
Wash thoroughly with soap and water after handling.
Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

STORAGE AND HANDLING

UCARCIDE™ 250 Antimicrobial is incompatible with many commonly used materials of construction such as steel, galvanized iron, aluminum, tin, and zinc. UCARCIDE™ 250 Antimicrobial can be stored and handled in baked phenolic-lined steel, polyethylene, stainless steel, or reinforced epoxy-plastic equipment. This product freezes at about -6° F (-21° C). Therefore, unless the storage tank is inside or underground, heating and insulation may be required. If heating is needed, exposure to high temperatures should be avoided. For short storage times (up to about 1 month), temperatures of up to 100° F (37.8° C) can be tolerated but the preferred maximum storage temperature is about 80° F (26.7° C).

A stainless steel centrifugal pump is suggested for transfer service. Spiral-wound stainless steel with TEFLON® Polymer is suitable for gaskets and packing.

Handle in a well-ventilated area. If vapors are irritating to the nose or eyes, special ventilation or respiratory protection (MSHA/NIOSH approved air purifying respirator equipped with an organic vapor cartridge) may be required.

LIMITED WARRANTY AND DISCLAIMER

Seller warrants that the product conforms to its chemical description as contained on this label and is reasonably fit for the purposes stated on this label when used in accordance with directions under normal conditions of use. THE WARRANTIES MADE IN THIS PARAGRAPH ARE SELLER'S SOLE WARRANTIES WITH RESPECT TO THE PRODUCT AND ARE MADE EXPRESSLY IN LIEU OF AND EXCLUDE ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE AND ALL OTHER EXPRESS OR IMPLIED REPRESENTATIONS AND WARRANTIES.

**BEFORE HANDLING OR USING THIS PRODUCT, SEE
YOUR EMPLOYER AND READ CURRENT MATERIAL
SAFETY DATA SHEET.**



65540-05/05/2008

NOTICE

**Do Not Ship or Store with Food,
Feeds, Drugs, or Clothing**

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

FOR FORMULATION OF INDUSTRIAL BACTERICIDES AND PRESERVATIVES FOR USE IN:

- AIR WASHERS AND INDUSTRIAL SCRUBBING SYSTEMS, RECIRCULATING COOLING AND PROCESS WATER SYSTEMS INCLUDING THOSE THAT CONTAIN REVERSE OSMOSIS MEMBRANES, SERVICE WATER AND AUXILIARY SYSTEMS, HEAT TRANSFER SYSTEMS, WASTEWATER SYSTEMS INCLUDING WASTEWATER SLUDGE AND HOLDING TANKS
- BEET SUGAR MILLS AND BEET SUGAR MILL PROCESS WATER SYSTEMS
- PAPER MILLS AND PAPER MILL PROCESS WATER SYSTEMS, PIGMENTS AND FILLER SLURRIES FOR PAPER AND PAPERBOARD, WATER BASED COATINGS FOR PAPER AND PAPERBOARD
- FUNCTIONAL FLUIDS AND LUBRICANTS AND AQUEOUS METALWORKING FLUIDS AND IN INDUSTRIAL, INSTITUTIONAL AND CONSUMER PROCESSES AND PRODUCTS IN AQUEOUS-BASED SOLUTIONS, SLURRIES AND EMULSIONS
- OIL WELL DRILLING, OIL FIELD PROCESSING APPLICATIONS, OIL FIELD WATER SYSTEMS, OIL AND GAS PRODUCTION AND TRANSMISSION PIPELINES AND SYSTEMS AND GAS STORAGE FIELDS AND EQUIPMENT SUCH AS STEAM-INJECTION WATER HOLDING TANKS, FLOOD WATER, FRACTURING FLUIDS, INJECTION WATER, HOLDING POND WATER, DISPOSAL-WELLWATER, WATER HOLDING TANKS, FUEL STORAGE TANKS AND RELATED REFINERY AND OILFIELD CLOSED, INDUSTRIAL RECIRCULATING WATER HANDLING SYSTEMS
- ANIMAL PRODUCTION FACILITIES AND FARM EQUIPMENT SUCH AS: POULTRY & TURKEY HOUSES, SWINE HOUSING AND FARROWING AREAS, BARNs AND LARGE ANIMAL BUILDINGS, HATCHERS, SETTERS AND CHICK PROCESSING FACILITIES, CAGES AND TRANSPORT VEHICLES, AND HATCHING EGGS AND FOR SANITIZING INDUSTRIAL OR NON-FOOD CONTACT SURFACES SUCH AS EQUIPMENT FOR MIXING, PACKING, OR PACKAGING PRODUCTS, PRODUCT TRANSFER LINES, STORAGE TANKS, FLOORS, AND WALLS.

STORAGE AND DISPOSAL

PESTICIDE DISPOSAL: Do not contaminate water, food or feed by storage or disposal. Open dumping is prohibited. Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or your Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Metal Containers or Plastic Containers: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or other procedures approved by state and local authorities. **Plastic Containers:** May be incinerated, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. **Metal Containers:** Must not be incinerated. Do not cut or crush metal containers.

ACCEPTED
with COMMENTS
EPA Letter Dated:

DEC 23 2008

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 464-691

Reg Number: 59106-I

Reg. Type: Product Registration - Section 3

Status: Under Review (03-Feb-2014)

Name: BIO CLEAR G50

[<View Registration Details>](#)

(No New Receipts)				
S:	Submission Type	OPP Rec'd Date	Resubmission	Description

- ...Decisions...
- Data Requirements
 - Pending: 487386 59106-I A532 UNREGISTERED
 - 75-Day Letters
 - S: 947069 2/3/2014; New Registration; 591

Decision Sequence: 487386

Action: A532 UNREGISTERED SOURCE OF ACTIVE INGREDIEN

Number: 59106-I

Original Decision:

Name: BIO CLEAR G50

Decision Status: PENDING (04-Feb-2014)

Organization Owner: AD / RMB1

Team Owner: RM 33

FFS Start Date 24-Feb-2014

Received by Risk Manager:

Due Date 24-Jul-2014

FFS Amt Expected: \$4,863

Negotiated Due Date:

FFS Amt Refunded:

FFS Amt Received: \$4,863

Comments:

Lantz, Tracy

From: Miederhoff, Eric
Sent: Wednesday, July 09, 2014 5:09 PM
To: Lantz, Tracy
Subject: RE: URGENT 75 day letters for 59106-I and 59106-O

Categories: Red Category

I spoke with Stan, made him aware that we will be sending him reviews w/deficiencies and a letter requesting a response on a path forward. He asked that we email these materials.

From: Lantz, Tracy
Sent: Wednesday, July 09, 2014 4:55 PM
To: Miederhoff, Eric
Subject: URGENT 75 day letters for 59106-I and 59106-O

Please call Stan and tell him we need to renegotiate.

Tracy Lantz

Antimicrobials Division
Office of Pesticide Programs
Environmental Protection Agency
(703) 308-6415
Lantz.tracy@epa.gov

From: Oslosky, Stanley [<mailto:Stanley.Oslosky@Weatherford.com>]
Sent: Tuesday, July 08, 2014 3:59 PM
To: Lantz, Tracy
Subject: RE: 59106-I and 59106-O Label corrections

Tracy,

I previously provided matrices that indicated that for certain data requirements, other than chemistry, that I wanted to use the cite-all method. I also provided with my submission a list of those submitters to whom I send offers-to-pay. Do you not have these documents?

Stan

From: Lantz, Tracy [<mailto:Lantz.Tracy@epa.gov>]
Sent: Tuesday, July 08, 2014 3:55 PM
To: Oslosky, Stanley
Cc: Miederhoff, Eric
Subject: RE: 59106-I and 59106-O Label corrections

Generic data is the data that supports the technical active ingredient. Since you are not purchasing the active ingredient from a registered source, you must address all of the generic data requirements. This is why I previously suggested you go to the RED for gluteraldehyde. (see the link I sent last week to this RED) Here you will be able to see the data that

was relied upon to support this ingredient and the uses associated with this ingredient. The uses on your label are pretty broad. I suggest you start there.

- In addition, here is the link to the list of data requirements based on the uses: http://www.epa.gov/oppfead1/cb/csb_page/updates/2013/data-require-antimicrobial.html
- Here is some general information on data compensation: <http://www.epa.gov/pesticides/bluebook/chapter10.html>
- If you decide to cite all method of support for any requirement, this list will be needed: <http://www.epa.gov/pesticides/DataSubmittersList/index.htm>

Tracy Lantz

Antimicrobials Division
Office of Pesticide Programs
Environmental Protection Agency
(703) 308-6415
Lantz.tracy@epa.gov

From: Oslosky, Stanley [<mailto:Stanley.Oslosky@Weatherford.com>]
Sent: Tuesday, July 08, 2014 2:43 PM
To: Lantz, Tracy
Subject: 59106-I and 59106-O Label corrections

Tracy,

Attached are the labels corrected and named as you have advised. Below are label with glutaraldehyde that have the some combination of the 4 uses that you have identified. [Sorry I guess I did not pick the best "me-too" product]. There are more I am sure if you need them I can do a more exhaustive search.

I hope to have the matrices to you by the end of the day, but wanted to get these to you as soon as I could.

Stan
724-316-0689

Myacide GA 50--- **Wastewater-Frac-MWF**
EPA Registration No. 33753-31

Myacide ® GA 2S--- **Wastewater-Frac-MWF—air washer etc**
EPA Registration No: 33753-26

UCARCIDETM 25 Antimicrobial—**Wastewater – Frac--MWF—air washer etc**
EPA Registration No. 464-688

UCARCIDETM 250 Antimicrobial---**Wastewater--MWF—air washer etc**
EPA Registration No. 464-691

UCARCIDE™ 45 Antimicrobial-- **Wastewater – Frac-MWF—air washer etc**
EPA Registration No 464 692

UCARCIDE™ 15 Antimicrobial-- **Wastewater – Frac-MWF—air washer etc**
EPA Registration No. 464-693

This message may contain confidential and privileged information. If it has been sent to you in error, please reply to advise the sender of the error and then immediately delete it. If you are not the intended recipient, do not read, copy, disclose or otherwise use this message. The sender disclaims any liability for such unauthorized use. PLEASE NOTE that all incoming e-mails sent to Weatherford e-mail accounts will be archived and may be scanned by us and/or by external service providers to detect and prevent threats to our systems, investigate illegal or inappropriate behavior, and/or eliminate unsolicited promotional e-mails (spam). This process could result in deletion of a legitimate e-mail before it is read by its intended recipient at our organization. Moreover, based on the scanning results, the full text of e-mails and attachments may be made available to Weatherford security and other personnel for review and appropriate action. If you have any concerns about this process, please contact us at dataprivacy@weatherford.com.

Lantz, Tracy

From: Lantz, Tracy
Sent: Tuesday, July 08, 2014 6:21 PM
To: Miederhoff, Eric
Cc: John Hebert (Hebert.John@epa.gov); Hicks, Karen
Subject: Two PRIA actions due 7/24 59106-O and 59106-I

Tracking:	Recipient	Delivery
	Miederhoff, Eric	Delivered: 7/8/2014 6:22 PM
	John Hebert (Hebert.John@epa.gov)	Delivered: 7/8/2014 6:22 PM
	Hicks, Karen	Delivered: 7/8/2014 6:22 PM
	[REDACTED]	Delivered: 7/8/2014 6:22 PM
	[REDACTED]	
	[REDACTED]	
	[REDACTED]	Delivered: 7/8/2014 6:22 PM

Hi Eric,

As you and I discussed last week and this week, I have a number of concerns associated with these two submissions and my ability to finish these actions before I leave on vacation. My last day in the office is Monday, July 14th. I will not return to the office until July 29th.

These submissions are due out on July 24th with a pre-decisional due date of July 10th (Thursday.)

I am glad to complete work on these submissions before I leave as long as I have the signed chemistry reviews in hand on Wednesday and can send the 75 day letters the same day, asking for the registrant to reply by Thursday the 10th. This will allow us to meet our pre-decisional date. I will then submit the renegotiations for signature on Thursday or Monday so that the renegotiations can be approved and entered into OPPIN before I leave the office.

If I do not have the signed chemistry reviews in hand on Wednesday in time for the completion of the 75 day letters, I expect that you will assign these submissions to someone else for completion. If I do not hear from you I will assume that you are assigning these actions to another reviewer.

History:

I received these submissions for Team 33 after they had already been in house for 2 months (rec'd by OPP on 2/3/14, rec'd by me on 4/1/14). I immediately worked with the our scientists on the screens. Juan was asked to perform a very quick screen since we only had 6 business days to complete the screen. Several chemistry deficiencies were identified. I sent a 10 day letter identifying these deficiencies to the 45th day, April 10th. We did not allow adequate time for this screening since the submissions were received by me two months late.

The company replied within 10 days with additional information. This revised package was sent to Chris for review. Chris did correspond with me via e-mail on May 8th indicating that the products had passed the technical screen. Unfortunately Chris was not able to make the chemistry review deadline of June 24th. I contacted Chris for updates on June 25th and June 30th. You and I spoke on July 1st about my concerns that Chris indicated that he would not be able to work on the review of this data until the week of July 7th. I felt this was too late as the pre-decisional date is July 10th. You asked that we obtain the packages from Chris and ask Karen Hicks if she would assign to another

Product ingredient source information may be entitled to confidential treatment

reviewer who could work on these the week of July 1st. When I spoke to you today, July 8th you said you had not heard from Karen. Chris spoke to me today, indicating that he could now work on these packages so we gave them back to Chris.

Chris has spoken to you and I several times today. The company is registering an MUP and end use product. He will use the MUP to formulate the end use. He has proposed the use of two unregistered sources, one from [REDACTED] the other made in [REDACTED] Chris says he does not have preliminary analysis data for both sources of AI and is uncertain if all of the other data requirements have been met. We asked him to report guideline by guideline and indicate if any of the requirements have not been addressed or if any of the data does not appear to be acceptable. We also asked that he complete this review tomorrow and provide a signed copy.

I have been in contact with the company since Wednesday the 2nd. I have reviewed the labels, me-too citations and data matrixes. I asked for numerous corrections and clarifications to each of these documents and have begun receiving replies from the registrant today. He has provided revised documents for review. I have not yet reviewed these. I told him in my correspondence last week that I did not have the final results of the chemistry reviews.

Thanks for your attention to these submissions and reassignment of these actions if I do not receive the final reviews early Wednesday the 9th.

Tracy Lantz

Antimicrobials Division
Office of Pesticide Programs
Environmental Protection Agency
(703) 308-6415
Lantz.tracy@epa.gov

Lantz, Tracy

From: Lantz, Tracy
Sent: Tuesday, July 08, 2014 2:25 PM
To: Miederhoff, Eric
Subject: FW: confusion on chemistry guideline numbers 59106-I and -O

Maybe the preliminary analysis was missed in the screen by both chemists.
Of course the screen is just the screen, but it does seem like this should have been caught.

Chris has preliminary analysis for one source, but it appears that he needs several other sets of this data since there are two unregistered sources.

Tracy Lantz

Antimicrobials Division
Office of Pesticide Programs
Environmental Protection Agency
(703) 308-6415
Lantz.tracy@epa.gov

From: Jiang, Chris
Sent: Tuesday, July 08, 2014 2:18 PM
To: Lantz, Tracy
Subject: RE: confusion on chemistry guideline numbers

No 830.1700 is the prelim anal. The other are phys chem

From: Lantz, Tracy
Sent: Tuesday, July 08, 2014 2:11 PM
To: Jiang, Chris
Cc: Miederhoff, Eric
Subject: confusion on chemistry guideline numbers

Is one of the guideline numbers listed below associated with the preliminary analysis?

830.1900,
830.6314,
830.6315,
830.6316,
830.6317,
830.6319,
830.6320,
830.7100

Tracy Lantz

Antimicrobials Division
Office of Pesticide Programs
Environmental Protection Agency
(703) 308-6415

Fee for Service

W
{947069N~

This package includes the following

☒ New Registration

☐ Amendment

☒ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ____

for Division

☒ AD

☐ BPPD

☐ RD

Risk Mgr. **33**

Receipt No.

S- **947069**

EPA File Symbol/Reg. No.

59106-I

Pin-Punch Date:

2/3/2014

☐ This item is NOT subject to FFS action.

Action Code:

Requested: **1532**

Granted: **1532**

Amount Due: \$ **4,863**

Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: *Team 1* Date: *2-4-14*

Remarks: *Not a new sub. per M-S-1111*

Receipt for Section 3



S: 947069 Milestone Email:

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Print Letter

Application Type: New Registration

Fee For Service: ☒ Yes ☐ No

Enter More Information

Billable: ☒ Yes ☐ No

Tracking

Company: 59106 CLEARWATER INTERNATIONAL, LLC



Risk Manager: Antimicrobials Division, Risk Management Team 33

Product #: 59106-I Product Name: BIO CLEAR G50

Override#:

Me Too Section3: 464-691 Me Too Product Name: UCARCIDE 250 ANTIMICROBIAL

Application Date: 27-Jan-2014

OPP Rec'd Date: 03-Feb-2014

Front End Date: 03-Feb-2014

Risk Manager Send Date:

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Receipt Content	
Study	
CSF	

Fast Track: ☐

New Ingredient: ☐

View/Edit

Receipt Description:

New product registration application

New Ingredient Request Date:

New Ingredient Received Date:

Form A: ☐ Signature Date:

Form B: ☐ Signature Date:

Oslosky, Stanley

From: paygovadmin@mail.doc.twai.gov
Sent: Wednesday, January 29, 2014 2:07 PM
To: Oslosky, Stanley
Subject: Pay.gov Payment Confirmation: PRIA Service Fees

Your payment has been submitted to Pay.gov and the details are below. If you have any questions or you wish to cancel this payment, please contact Pay.gov Customer Service by phone at (800) 624-1373 or by email at pay.gov.clev@clev.frb.org.

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 25E5ONAT
Agency Tracking ID: 74564001118
Transaction Type: Sale
Transaction Date: Jan 29, 2014 2:07:12 PM

Account Holder Name: Lara Leur
Transaction Amount: \$4,863.00
Billing Address: 2000 St, James Pl
City: Houston
State/Province: TX
Zip/Postal Code: 77056
Country: USA
Card Type: Visa
Card Number: *****9337

Decision Number:
Registration Number:
Company Name: Clearwater International Company Number: 59106 Action Code: A532

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

February 4, 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-487386
EPA File Symbol or Registration Number: 59106-I
Product Name: BIO CLEAR G50
EPA Receipt Date: 03-Feb-2014
EPA Company Number: 59106
Company Name: CLEARWATER INTERNATIONAL, LLC

STANLEY OSLOSKY
CLEARWATER INTERNATIONAL, LLC
D/B/A WEATHERFORD ENGINEERED CHEMISTRY
2000 ST. JAMES PLACE, 7TH FLOOR
HOUSTON, TX 77056-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: A532

UNREGISTERED SOURCE OF ACTIVE INGREDIENT;NEW PRODUCT;CITE-ALL DATA CITATION EXCEPT FOR PRODUCT CHEMISTRY;IDENTICAL OR SUBSTANTIALLY SIMILAR IN COMPOSITION AND USE TO A REGISTERED PRODUCT;PRODUCT CHEMISTRY DATA SUBMITTED;REGISTERED ACTIVE INGREDIENT;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-6427.

Sincerely,

Peresa Downs
Front End Processing Staff

Information Technology & Resources Management Division

A532 – New product identical or substantially similar in composition and use to registered product.

- Registered active ingredient, unregistered source of active ingredient.
- Cite all data citation except for product chemistry. Must submit Group A and B product chemistry data for the end use product as well as the unregistered source.

End Use (EP) or Manufacturing Use (MP) product or Technical Grade of the Active Ingredient (TGAI)

Guideline No.	Group A: Product Chemistry Data Study Title	EP Data Submitted	MP Data Submitted	TGAI Data Submitted
830.1550	Product Identity & Composition		✓	
830.1600	Description of materials used to produce the product		✓	
830.1650	Description of formulation process			
830.1670	Discussion on the formation of impurities		✓	
830.1700	Preliminary analysis		✓	
830.1750	Certified limits (158.345)		✓	
830.1800	Enforcement analytical method		✓	

Guideline No.	Group B: Product Chemistry Data Study Title	EP Data Submitted	MP Data Submitted	TGAI Data Submitted
830.6302	Color		✓	
830.6303	Physical State		✓	
830.6304	Odor		✓	
830.6313	Stability to normal and elevated temperatures metal and metal ions			
830.6314	Oxidation/Reduction (Chemical incompatibility)		✓	
830.6315	Flammability		✓	
830.6316	Explodability		✓	
830.6317	Storage stability*		✓	
830.6319	Miscibility		✓	
830.6320	Corrosion Characteristics*		✓	
830.6321	Dielectric Breakdown Voltage			
830.7000	pH		✓	
830.7050	UV/ Visible Absorption			
830.7100	Viscosity			
830.7200	Melting Point			
830.7220	Boiling Point			
830.7300	Density		✓	
830.7370	Dissociation Constant			
830.7550	Partition Coefficient			
830.7840	Water Solubility			
830.7950	Vapor Pressure			

Grayed out = data not required

*May not be included with initial application

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 2-3-14

Experts In-Processing Signature: B.B.

Date 2-5-14

Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>59106-I</u>		EPA Receipt Date: <u>2-3-14</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
	<u>*no inerts to review</u>					
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent					
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use)	yes	no			
	b) Cite-All (Fee category experts use)	X				
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of <u>Label</u> (<u>Electronic labels on CD</u> are encouraged and guidance is available)			X		
7	Is the data package consistent with <u>PR Notice 86-5</u>			X		
8	<u>Notice of Filing</u> included with petitions					X

9	If applicable for conventional applications, <u>reduced risk rationale</u>			X
10	<u>Required Data</u> and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

Comments:

* Submitted studies PASSED PRN 11-3 review
 [REDACTED] and [REDACTED] only, no inerts to review
 * Contacted registrant on 02/12/14 to inform them of
 deficiencies with the certification form
 * Registrant submitted corrections on 02/12/14
 * Jacket PASSED

Inert ingredient information may be entitled to confidential treatment

EM

MBID: 493101

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the [inert Web site](#) and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the [Chief of Microbial Pesticides Branch](#).

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

McVearry, Emily

From: McVearry, Emily
Sent: Wednesday, February 12, 2014 9:19 AM
To: 'Oslosky, Stanley'
Cc: Ashe, Anthony
Subject: RE: Submission to EPA: Product Bio Clear G50 (EPA Reg# 59106-I)

Hi Stan,

Thank you for sending me the corrections, they look great! I will go ahead and insert the corrections, and send your application to the appropriate Product Manager today.

Best regards,

Emily A. McVearry
EPA Contractor
2777 S. Crystal Drive, S-4825
Arlington, VA 22202
Ph: (703) 347-8003
Fax: (703) 305-5060
mcvearry.emily@epa.gov

From: Oslosky, Stanley [<mailto:Stanley.Oslosky@Weatherford.com>]
Sent: Wednesday, February 12, 2014 8:53 AM
To: McVearry, Emily
Cc: Ashe, Anthony
Subject: RE: Submission to EPA: Product Bio Clear G50 (EPA Reg# 59106-I)

Dear Emily,

Attached is a copy corrected as per your instructions.

Best regards,
Stan Oslosky
724-316-0689

From: McVearry, Emily [<mailto:McVearry.Emily@epa.gov>]
Sent: Wednesday, February 12, 2014 7:05 AM
To: Oslosky, Stanley
Cc: Ashe, Anthony
Subject: Submission to EPA: Product Bio Clear G50 (EPA Reg# 59106-I)

Good Afternoon, Mr. Oslosky:

This e-mail is to address an issue with your application for registration of product Bio Clear G50 (EPA Reg# 59106-I):

Deficiencies with the submitted The Certification with Respect to Citation of Data form

If you wish to cite-all and own data, the second box under Section I: Method of Data Support must be checked. The second box states, *"I am using the selective method of support (or cite-all option under the selective method) and have included with this form a completed list of data requirements (the Data Matrix form must be used"*.

Please verify and send the corrections either by e-mail or through our secure fax line. I will need the corrections by Monday, February 17th. If you have any questions, please do not hesitate to contact me.

Best Regards,

Emily A. McVearry
EPA Contractor
2777 S. Crystal Drive, S-4825
Arlington, VA 22202
Ph: (703) 347-8003
Fax: (703) 305-5060
mcvearry.emily@epa.gov

This message may contain confidential and privileged information. If it has been sent to you in error, please reply to advise the sender of the error and then immediately delete it. If you are not the intended recipient, do not read, copy, disclose or otherwise use this message. The sender disclaims any liability for such unauthorized use. PLEASE NOTE that all incoming e-mails sent to Weatherford e-mail accounts will be archived and may be scanned by us and/or by external service providers to detect and prevent threats to our systems, investigate illegal or inappropriate behavior, and/or eliminate unsolicited promotional e-mails (spam). This process could result in deletion of a legitimate e-mail before it is read by its intended recipient at our organization. Moreover, based on the scanning results, the full text of e-mails and attachments may be made available to Weatherford security and other personnel for review and appropriate action. If you have any concerns about this process, please contact us at dataprivacy@weatherford.com.



Weatherford

BioClear G50 Antimicrobial

FOR MANUFACTURING USE ONLY

Active ingredient

Glutaraldehyde.....	51.1%
Inert ingredients.....	48.9%
Total.....	100%

PRECAUTIONARY STATEMENTS HAZARD TO HUMANS AND DOMESTIC ANIMALS

DANGER

Keep Out of Reach of Children

DANGER! Corrosive. Causes irreversible eye damage. Causes skin burns. Harmful if inhaled. May be fatal if swallowed. Harmful if absorbed through skin. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Causes asthmatic symptom in hyper-sensitive individuals.

Do not get in eyes, on skin or on clothing. Do not swallow. Avoid breathing vapor. Wear goggles or face shield and protective clothing and glove made of butyl or nitrile rubber. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse. Handle in a well-ventilated area. If vapors are irritating to the nose or eyes, special ventilation or respiratory protection (MSHA/NIOSH approved air purifying respirator equipped with an organic vapor cartridge) may be required.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

Manufactured for:

CLEARWATER INTERNATIONAL, LLC
D/B/A WEATHERFORD ENGINEERED
CHEMISTRY
2000 St. James Place
Houston, TX 77056
713-836-4000

STORAGE AND HANDLING

BIOCLEAR G50 Antimicrobial is incompatible with many commonly used materials of construction such as steel, galvanized iron, aluminum, tin, and zinc. BIOCLEAR G50 Antimicrobial can be stored and handled in baked phenolic-lined steel, polyethylene, stainless steel, or reinforced epoxy-plastic equipment. This product freezes at about 27 °F (-3 °C). Therefore, unless the storage tank is inside or underground, heating and insulation may be required. If heating is needed, exposure to high temperatures should be avoided. For short storage times (up to about 1 month), temperatures of up to 100 °F (37.8 °C) can be tolerated but the preferred maximum storage temperature is about 80 °F (26.7 °C). A stainless steel centrifugal pump is suggested for transfer service. Spiral-wound stainless steel with TEFLON® Polymer is suitable for gaskets and packing.

STORAGE AND DISPOSAL

PESTICIDE DISPOSAL: Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL

Non-refillable container: Do not reuse or refill this container. Triple rinse or pressure rinse container (or equivalent) promptly after emptying. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

Refillable Container: Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning of the container is the responsibility of the person disposing of the container. Cleaning the container before refilling is the responsibility of the person refilling the container. To clean the container before final disposal, empty contents into application equipment and triple rinse. Pour or pump rinsate into application equipment or rinsate collection system. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

First Aid

If swallowed:	• Call a poison control center or doctor immediately for treatment advice. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything to drink.
If in eyes:	• Hold eye open and rinse immediately and completely with water for at least 30 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Obtain prompt medical consultation. • Call a poison control center or doctor for treatment advice
If on skin or clothing	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice
If Inhaled	• Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For emergency information call the National Pesticides Information Center at 1-800-858-7378, 6:30 AM to 4:30 PM Pacific Time (PT), seven days a week. During other times, call the poison control center at 1-800-222-1222.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This product may be used for the formulation of pesticide products. Formulators using this product are responsible for obtaining EPA registrations for their formulated products.

For use in the formulation of antimicrobial Products in the following applications:

Oil Field Preservatives

- Oil and gas production
- Drilling, completion and workover fluids
- Packer fluids
- Gas storage
- Hydrotesting
- Pipeline
- Frac fluids
- Water floods

Industrial Processes and Water Systems

- Air washers
- Service water and ancillary non-potable systems
- Heat transfer systems
- Industrial wastewater systems including those with reverse osmosis membranes
- Aqueous metal working systems

EPA registration # 59106-XX

EPA establishment #: _____

Net contents: _____ LBS. _____ KG.



Office of Pesticide Programs (7504P) REGFEE
U. S. Environmental Protection Agency
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

January 29, 2014

ATTENTION: Marshall Swindell
Product Manager, Team 33

SUBJECT: Clearwater International, LLC d/b/a Weatherford Engineered Chemistry (59106)
BioClear G50 Antimicrobial and BioClear 2500 Antimicrobial
Registration applications

Dear Marshall;

On behalf of Clearwater International, LLC, I am submitting applications for the registration of the above two products. Both are an approximate 50% solution of Glutaraldehyde and are chemically identical. Clearwater is applying for BioClear G50 as a Manufacturing Use Product and BioClear 2500 as an End Use Product. All required document are enclosed and formatted.

1. BioClear G50 Antimicrobial –MUP
2. BioClear 2500 Antimicrobial –EUP

Thank you for your assistance with this application and if you or your staff have any questions, please call me at 724-316-0689 or e-mail me at Stanley.oslosky@weatherford.com.

Sincerely,

Stan Oslosky
Consultant to Weatherford
Stanley.Oslosky@weatherford.com

Engineered Chemistry

Weatherford
2000 St. James Place
Houston, Texas 77056
USA

+1.713.968.4000
+1.713.969.2401 Fax

www.weatherford.com



United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company / Product Number 59106-xx	2. EPA Product Manager Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company / Product (Name) BioClear G50	PM# 33	
5. Name and Address of Applicant (include ZIP Code) CLEARWATER INTERNATIONAL, LLC D/B/A WEATHERFORD ENGINEERED CHEMISTRY 2000 ST. JAMES PLACE, 7th Floor HOUSTON, TX 770956 <input type="checkbox"/> Check of this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. <u>464-691</u> Product Name <u>Ucarcide 250</u>	

Section - II

<input type="checkbox"/> Amendment - Explain Below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input checked="" type="checkbox"/> "Me Too" Application
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This is an EPA Number A532. This is an MUP with a new source of a previously registered active. This new product is chemically identical to the above referenced products. A five batch analysis is provided.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt. _____ No. per container _____	Water Soluble Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Package Wgt _____ No. per container _____	<input checked="" type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify) Baked Phenolic-line steel		
* Certification must be submitted					
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) retail Container 25 kg box		5. Location of Label Directions Container	
6. Manner in Which Label is affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glues <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary. To process this application.)		
Name Stan Oslosky	Title Consultant to Weatherford	Telephone No. (Include Area Code) 724-316-0689
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Consultant to Weatherford	
4. Typed Name Stan Oslosky	5. Date 27-Jan-14	

TRANSMITTAL DOCUMENT

Transmittal Date: January 30, 2014
Name and Address of Submitter: CLEARWATER INTERNATIONAL LLC, D/B/A WEATHERFORD
ENGINEERED CHEMISTRY
HOUSTON, TX 77056
**Regulatory action in support of which
this package is submitted:** *Information to support the registration of BioClear G50 (MUP)*
EPA Reg. No./File Symbol: 59106-XX
Alternate test material name Glutaraldehyde

Administrative Materials

	Transmittal Document
	Cover Letter
	Pay.gov acknowledgement e-mail
	List of AEATF II member companies
EPA Form 8570-1	Application for Pesticide
	Label (5 copies)
EPA Form 8570-4	Confidential statement of formula (3 copies)
EPA Form 8570-34	Certification with Respect to Citation of Data
EPA Form 8570-35	Data Matrix—Listing Offer-to-pay recipients
EPA Form 8570-35	Data Matrix
EPA Form 8570-35	Data Matrix (masked)

Volume No.	Citation	MRID Number
1	Oslosky, 2014, Product Chemistry Data. Unpublished study by Clearwater International d/b/a Weatherford, 7 pages. With Confidential Attachment 17 pages. (3 copies).	
2	Valla, Sept. 27, 2013; Glutaraldehyde Technical: Preliminary Analysis. Unpublished study by Eurofins Product Safety Laboratories 20 pages. Confidential Attachment 5 pages (3 copies).	
3	Wo, Sept. 27, 2013; Glutaraldehyde Technical: Physical and Chemical Characteristics: Color, Physical State, Odor, Stability to Normal and Elevated Temperatures, pH, UV/Visible Absorption, Boiling Point, Density/Relative Density, Dissociation Constant, Partition Coefficient and Water Solubility. Unpublished study by Eurofins, Product Safety Laboratories 38 pages. (3 copies).	
4	Cage, Oct. 16, 2012; Glutaraldehyde Technical: Vapor Pressure. Unpublished study by Huntington Life Sciences Ltd., 18 pages. (3 copies).	
7	Oslosky, 2014, Waiver Request for Product Chemistry Data. Unpublished study by Clearwater International d/b/a Weatherford, 6 pages.	

Product: BioClear G50
Submitter Stan Oslosky
Company: CLEARWATER INTERNATIONAL LLC, D/B/A WEATHERFORD ENGINEERED
CHEMISTRY
Phone: 724-316-0689
E-mail: Stsnley.Oslosky@Weatherford.com

***Note to reviewer—A concurrent EUP that is chemically identical is also being submitted for which the above studies are also relevant**

